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POWER TO SAVE A LIFE

HEARTSTART.
## FR2+ DEFIBRILLATOR
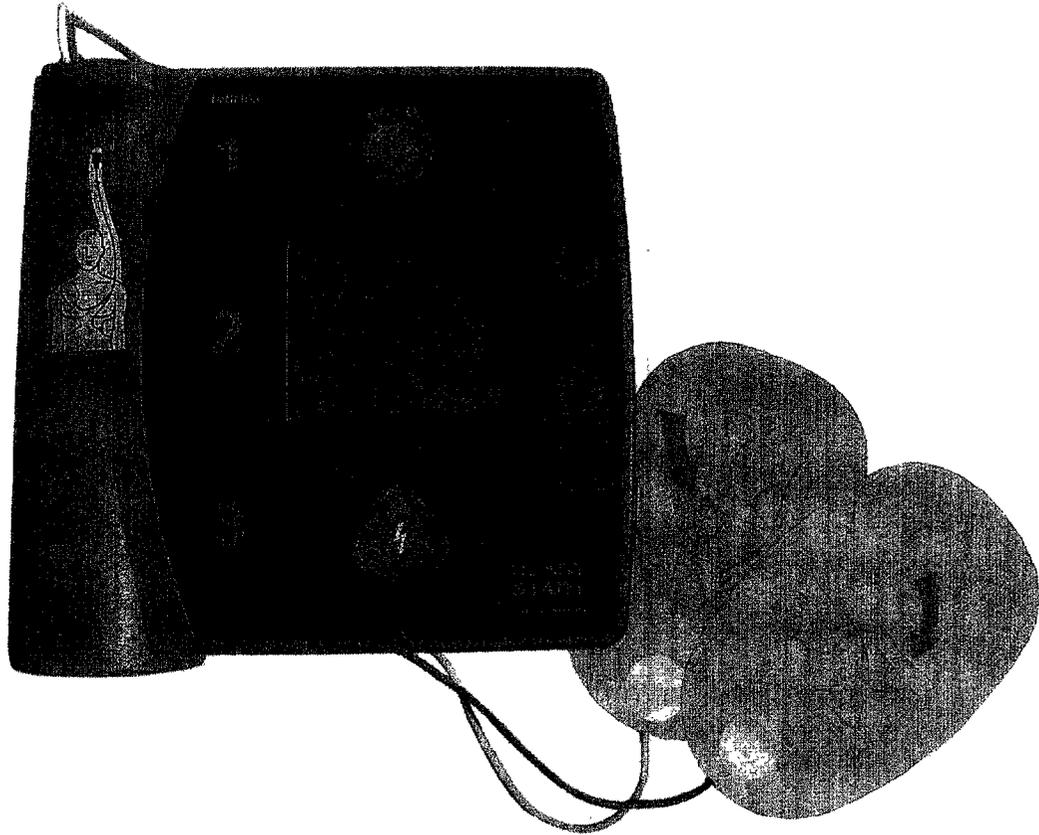
HEARTSTART FR2+ DEFIBRILLATOR
INSTRUCTIONS FOR USE

PHILIPS

M3860A, M3861A
Edition 10
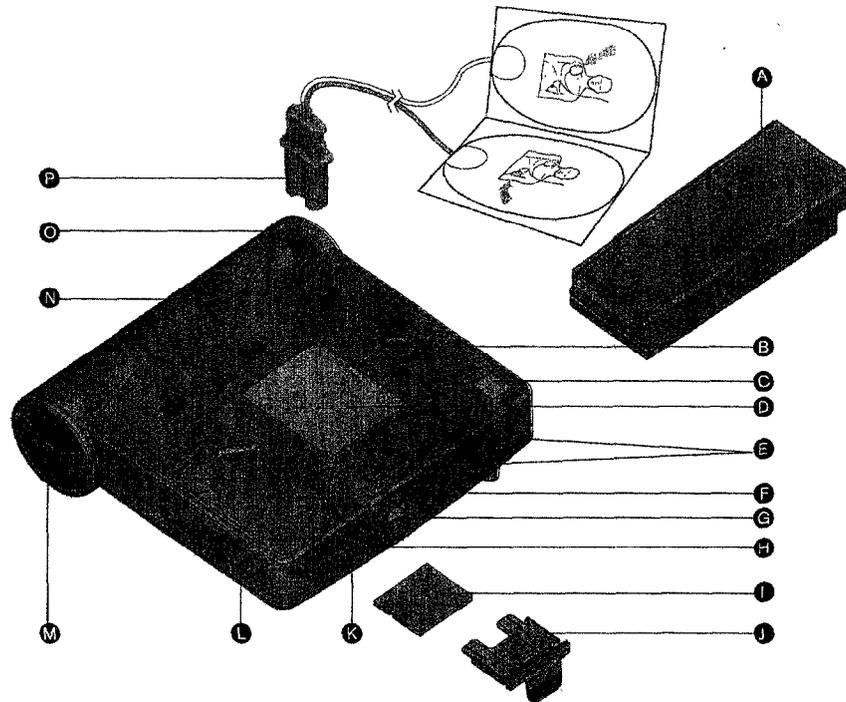
The HeartStart FR2+ Defibrillator

Clockwise from top right.

Ⓐ Battery. Standard long-life or rechargeable battery used to power the FR2+. (Check local regulations for disposal and recycling requirements.)

Ⓑ On/Off button. Turns on the FR2+ and starts voice and screen prompts. Second press turns off the FR2+.

Ⓒ Status Indicator. Shows you the readiness status of the FR2+.

Ⓓ Display screen. Displays text prompts and incident data. The FR2+ M3860A screen also displays the patient's ECG.

Ⓔ Option buttons. Adjust the contrast of the screen display and control special functions.

Ⓕ Beeper port. Broadcasts alert beeps when required. It is located under the right edge of the FR2+.

Ⓖ Infrared (IR) communications port. A special lens, or "eye," used to transfer data directly to or from another device.

Ⓗ Data card port. Receptacle for data card tray.

Ⓘ Data card (optional). Used to store and review information about an incident, including ECG and optional voice recording.

Ⓙ Data card tray. Special sleeve that holds the data card and fits into the data card port to help seal the FR2+ against fluids. *The tray should be kept installed in the FR2+ even if no data card is used.*

Ⓚ Microphone. Used optionally to record surrounding audio during an incident. It is located under the right edge of the FR2+.

Ⓛ Shock button. Controls shock delivery. The button flashes when the HeartStart FR2+ is ready to deliver a shock.

Ⓜ Speaker. Amplifies voice prompts during use of the FR2+.

Ⓝ Pads placement diagram. Illustrates correct placement of pads. *Diagrams are also shown on the defibrillator pads.*

Ⓞ Defibrillator pads connector socket. Receptacle for connector of the defibrillator pads cable. An adjacent LED light flashes to show socket location and is covered when connector is inserted.

**Ⓟ Adult defibrillator pads.** Self-adhesive pads with attached cable and connector.

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# HEARTSTART FR2+ DEFIBRILLATOR
QUICK REFERENCE CARD

IF PATIENT IS UNRESPONSIVE AND NOT BREATHING NORMALLY:

TURN ON
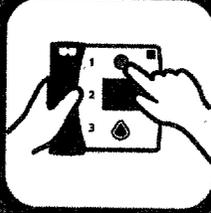
FOLLOW PROMPTS
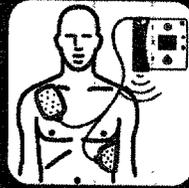
PRESS SHOCK BUTTON IF INSTRUCTED
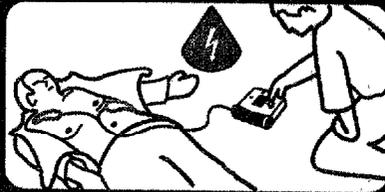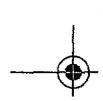
Intentionally left blank.

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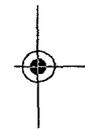
HEARTSTART FR2+
M3860A, M3861A Defibrillator

INSTRUCTIONS FOR USE

Edition 10

Philips Medical Systems

PHILIPS

Instructions for Use

Equipment specifications are subject to alteration without notice. All changes will be in compliance with regulations governing manufacture of medical equipment.

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CAUTION

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

The HeartStart FR2+ is designed to be used only with Philips-approved accessories. The HeartStart FR2+ may perform improperly if non-approved accessories are used.

Device Tracking

In the U.S.A., this device is subject to tracking requirements by the manufacturer and distributors. If the defibrillator has been sold, donated, lost, stolen, exported, or destroyed, notify Philips Medical Systems or your distributor.

Device Manufacturer

The HeartStart FR2+ Defibrillator is manufactured by Philips Medical Systems, Seattle, Washington, USA.

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B Technical Specifications

C Glossary of Symbols and Controls

D Glossary of Terms

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M3860A/M3861A HEARTSTART FR2+

1 Introduction to the HeartStart FR2+

What is the HeartStart FR2+?

The HeartStart FR2+ Defibrillator ("FR2+") is an automated external defibrillator. It is compact, lightweight, portable, and battery powered. It is designed for simple and reliable operation by a trained responder.

NOTE: The HeartStart FR2+ is an enhanced version of the defibrillator previously sold as the Heartstream FR2. The FR2+ has all the features of the FR2. All accessories compatible with the FR2 are also compatible with the FR2+. However, the FR2+ has some new features not present in the FR2 and can be used with certain accessories (labeled FR2+) that are not compatible with the FR2.

The FR2+ has a Status Indicator that is always active, so you can tell at a glance if it is ready for use. The front panel of the FR2+ has an On/Off button at the top and a Shock button at the bottom. A display screen in the center of the panel provides text prompts and incident information. Voice prompts are provided through a speaker located at the base of the FR2+. (See the diagram on the inside front cover for details.)

The FR2+ is available in two models, the M3860A and the M3861A. They share a set of basic features, detailed in Chapter 6. The principle differences between the two models are identified below:

model M3860A	model M3861A
Configurable ECG display on screen	Text prompt display on screen, no ECG display
Configurable manual charge in advanced mode	No manual charge in advanced mode

NOTE: The FR2+ comes with a factory default setup that can be modified. (See Chapter 6, "Setup and Advanced Mode Features," for a description of setup defaults and options.)

When Is the HeartStart FR2+ Used?

The HeartStart FR2+ Defibrillator is used with disposable defibrillator pads applied to a person who is experiencing the symptoms of sudden cardiac arrest (SCA): lack of responsiveness and lack of breathing. *Defibrillation should not be performed on anyone who is responsive or is breathing.*

Infant/child reduced-energy defibrillator pads are available for use with the FR2+ on children under the age of 8 or weighing less than 55 pounds (25 kg).

The FR2+ is intended for use by emergency care personnel who have been specifically trained in the operation of the FR2+ or who are qualified by training in Basic Life Support (BLS), in Advanced Life Support (ALS), or in other physician-authorized emergency medical response.

At the discretion of emergency care personnel, the M3860A FR2+ with ECG display enabled can also be used with the FR2+ ECG assessment module to display the rhythm of a responsive or breathing patient, regardless of age. The FR2+ Defibrillator used with the FR2+ ECG assessment module provides a non-diagnostic display for attended patient monitoring. While connected to the FR2+ ECG assessment module, the FR2+ displays and evaluates the patient's ECG and disables its shock capability.

How Does the HeartStart FR2+ Work?

The HeartStart FR2+ Defibrillator is designed to provide external defibrillation therapy to someone in cardiac arrest. Defibrillation therapy is the best available way to treat a variety of potentially fatal heart arrhythmias.

The FR2+ is extremely easy to use. When connected to defibrillator pads that are properly applied to the patient's bare chest, the FR2+:

1. prompts you to take specific actions,

2. automatically analyzes the patient's heart rhythm and advises you whether or not the rhythm is shockable, and

3. arms the Shock button, if appropriate, and instructs you to press it to deliver a biphasic electric pulse designed to defibrillate the heart.

Detailed instructions for use are provided in Chapter 3.

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How Is the HeartStart FR2+ Supplied?

The HeartStart FR2+ Defibrillator is supplied with a standard long-life battery, two sets of adult defibrillator pads with integrated cable and connector, and a data card tray. Other accessories, including an FR2+ rechargeable battery, FR2 infant/child reduced-energy defibrillator pads, and (for M3860A only, with ECG display enabled) a three-wire FR2+ ECG assessment module, are available. See Appendix A for a list of accessories and other recommended supplies.

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2 Preparing Your HeartStart FR2+ for Use

Overview

There are a few basic steps to preparing your HeartStart FR2+ Defibrillator for use:

- Install data card (optional).
- Install a battery.
- Set the clock in the FR2+ (optional).
- Run the battery insertion selftest.
- Place the FR2+ with recommended accessories in a convenient location.

The instructions presented here briefly describe the normal sequence of preparation. *It assumes that you are using a fresh battery, that the selftest passes, that you are not using a data card, and that the factory default settings will not be changed.* Exceptions to this sequence are provided elsewhere in this manual.

Installing the Battery

The HeartStart FR2+ Defibrillator is shipped with a M3863A standard, long-life battery. The battery is enclosed in a gray plastic case. There is a yellow latch at one end that holds the battery in place when it is correctly installed in the FR2+. (The optional M3848A FR2+ rechargeable battery is enclosed in a blue plastic case and also has a yellow latch. Except where otherwise noted, the following information applies to both battery types.)

Before installing the battery, make sure the defibrillator pads are not connected to the FR2+. To install the battery:

1. Hold the battery by the latch end and slide it into the battery compartment at the top of the FR2+.

2. Slide the battery all the way into the opening, until the latch clicks into place. The latch will click into place only when the battery is inserted correctly.

CAUTION: Follow all instructions supplied with the HeartStart M3863A standard battery. Install the battery before the install-by date shown on the battery.

2-2

```
┌─────────────────────────┐
│     RUN SELFTEST        │
│    REVIEW INCIDENT      │
│    NO DATA CARD         │
│    GOOD BATTERY         │
│       NEXT              │
├─────────────────────────┤
│    IN EMERGENCY         │
│   PRESS OFF TO QUIT     │
└─────────────────────────┘
```

```
┌─────────────────────────┐
│     RUN SELFTEST        │
│    REVIEW INCIDENT      │
│    NO DATA CARD         │
│   0% ▓▓▓▓▓□ 100%        │
│       NEXT              │
├─────────────────────────┤
│    IN EMERGENCY         │
│   PRESS OFF TO QUIT     │
└─────────────────────────┘
```
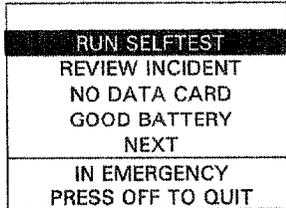
When the battery is installed, the FR2+ automatically turns on. The Status Indicator displays a flashing black hourglass. The Shock button light and the indicator light for the defibrillator pads connector socket turn on briefly.

The display screen brings up the main menu. From this menu, you can start the FR2+ battery insertion selftest, review information from the last time the FR2+ was used, or go to the next screen for other options. Information about the optional data card and the battery status is also provided. (See Chapter 7, "Data Management and Review," for details about reviewing an incident and using a data card.) For the M3863A standard battery, a GOOD BATTERY message should be displayed. For the M3848A FR2+ rechargeable battery, a "fuel gauge" graphic illustrates remaining power. Throughout the remainder of this manual, the screen displays illustrated will be for the standard battery unless otherwise noted.
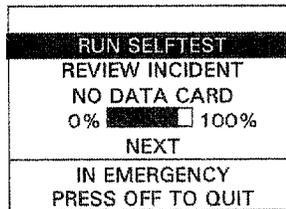
NOTE: This screen will *not* be displayed if the FR2+ is connected to defibrillator pads (that are applied to the patient) when the battery is inserted, and you will not be able to access the menu items. In addition, the battery insertion selftest and periodic automatic selftests cannot run while the defibrillator pads are connected to the patient. *Be sure to unplug the pads connector from the FR2+ after each use. Do not store the FR2+ with the pads connected.*

NOTE: To move around the menus displayed, use the Option buttons as follows:
- Press the LOWER Option button to move the highlight bar from one item to another on the menu.
- Press the UPPER Option button to select the highlighted item or to scroll through the settings for that item.

```
┌─────────────────────────┐
│    DEVICE HISTORY       │
│   BATTERY HISTORY       │
│       SETUP             │
│       CLOCK             │
│      RETURN             │
├─────────────────────────┤
│    IN EMERGENCY         │
│   PRESS OFF TO QUIT     │
└─────────────────────────┘
```
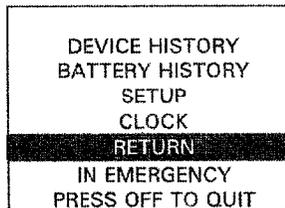
If you select NEXT, the menu displayed lets you review the history of the FR2+, review the history of the battery being used, access setup data, set the clock, or return to the first menu. (See Chapter 4, "Maintaining, Testing, and Troubleshooting Your HeartStart FR2+," for details about the review options and Chapter 6, "Setup and Advanced Mode Features," for information on the setup option.)

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M3860A/M3861A HEARTSTART FR2+

2

NOTE: *If you make no selection for 10 seconds, the selftest will automatically run.* If you want to select something different from either of these menus, you must do so before the selftest begins, or remove and reinstall the battery to bring up the main menu. You can press the On/Off button at any time to turn off the FR2+ and return it to standby (ready for use) mode. To use the FR2+, press the On/Off button again.

```
RUN SELFTEST
REVIEW INCIDENT
NO DATA CARD
GOOD BATTERY
NEXT
IN EMERGENCY
PRESS OFF TO QUIT
```

```
DEVICE HISTORY
BATTERY HISTORY
SETUP
CLOCK
RETURN
IN EMERGENCY
PRESS OFF TO QUIT
```

```
CLOCK
RETURN
RECEIVE TIME
SEND TIME

07 / 09 / 00
DD / MM / YY
14 : 28
```
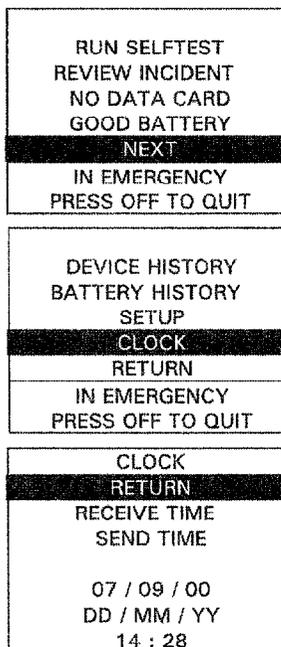
Setting the Clock

It is recommended that the first time you prepare your HeartStart FR2+ Defibrillator for use, you check the FR2+'s internal clock to be sure it is set to the correct date and local time. You can reset it if necessary.

To see the clock settings, select NEXT from the first menu, within 10 seconds of installing the battery, and then select CLOCK. To do this:

1. Press the lower Option button to move the highlight bar to NEXT.

2. Press the upper Option button to bring up the NEXT screen.

3. Press the lower Option button to move the highlight bar to CLOCK.

4. Press the upper Option button to bring up the CLOCK screen.

The CLOCK screen displays the date and time currently set in the internal clock of the FR2+.

NOTE: The date is displayed as day (DD), month (MM), and year (YY), as shown on the screen. The time is displayed using the 24-hour international clock.

If no changes to the clock settings are needed, select RETURN and go back to the first menu. If the date and time are not correct, there are two ways to set them:

*   Receive the clock settings from another FR2+ or from a computer using HeartStart Event Review® software,* using the RECEIVE TIME option. This may be used to synchronize the clocks of several FR2+s. You can also send the clock settings from one FR2+ to another one, using the SEND TIME option. See Chapter 6, "Setup and Advanced Mode Features," for instructions.

*   Manually set the date and the time.

* HeartStart Event Review software was previously sold as CodeRunner software.

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2-4
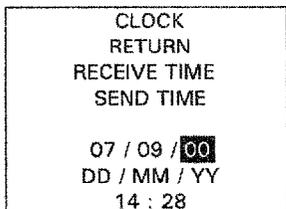
To manually set the clock:

```
CLOCK
RETURN
RECEIVE TIME
SEND TIME

07 / 09 / 00
DD / MM / YY
14 : 28
```

1. Use the lower Option button to move the highlight bar to the part of the clock setting you want to change.

2. Press the upper Option button repeatedly to scroll through the settings until you reach the one you want. If you go past it, keep scrolling until it comes up again.

3. Use the lower Option button to select the next part you want to change, and repeat the process, until all parts of the date and time have been set.

4. When you have made all the changes, move the highlight bar to RETURN and press the upper Option button to go back to the main menu screen.

NOTE: New clock settings are used by the FR2+ as soon as you set them. The clock time display is updated each minute this screen is displayed. The clock seconds, although not displayed, are set to 00 when you move the highlight bar out of the time settings.

NOTE: If the battery is removed from the FR2+ for more than two hours, the clock settings will be lost and must be reset.

Running the Battery Insertion Selftest

Except in an emergency, it is recommended that you run this selftest every time you change the battery. Make sure the defibrillator pads are not connected to the HeartStart FR2+ Defibrillator before running the battery insertion selftest.

The selftest has two parts. The first part automatically tests the FR2+ circuitry. The second part is interactive and requires you to respond to prompts in order to make sure the display, buttons, lights, speaker, and beeper of the FR2+ are working properly. (See Chapter 4, "Maintaining, Testing, and Troubleshooting Your HeartStart FR2+," for details about this selftest.)

```
RUN SELFTEST
REVIEW INCIDENT
NO DATA CARD
GOOD BATTERY
NEXT
IN EMERGENCY
PRESS OFF TO QUIT
```
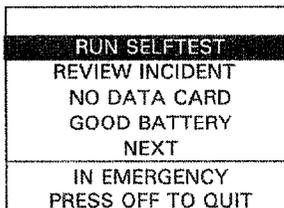
To run the selftest:

1. Make sure the defibrillator pads are not connected to the device.

2. Insert the battery into the battery port. The first screen displayed has RUN SELFTEST highlighted.

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M3860A/M3861A HEARTSTART FR2+

3. Press the upper Option button to activate the test.

4. OR make no selection for 10 seconds, and the selftest will start automatically if the FR2+ has been turned off for at least 5 minutes.

NOTE: If you connect defibrillator pads (that are applied to the patient) to the FR2+ during a battery insertion selftest, the selftest will stop and the FR2+ will go to its standby mode to be ready for use.

```
SELFTEST PASSED
REV:      XXX X.X XXXX
      NO DATA CARD

      SN 000000001
    IN EMERGENCY
  PRESS OFF TO QUIT
```

When the automatic part of the selftest is successfully completed, the screen displays a message that the test has passed, and then automatically starts the interactive part of the selftest. It is important to press the buttons and verify the indicators to ensure that the FR2+ will be ready for use.

When the entire selftest is complete, the FR2+ automatically turns off and returns to standby mode. In the standby mode, the Status Indicator displays a flashing black hourglass. This means that the FR2+ has passed its most recent self-test and is therefore ready for use, simply by pressing the On/Off button to turn it on.

Placing and Securing the HeartStart FR2+

Place the HeartStart FR2+ Defibrillator in an accessible area with the Status Indicator easily visible. Useful accessories for placing and securing the FR2+ include a carrying case, which is suitable for use with a wall mount bracket or defibrillator cabinet. (See Appendix A for a list of accessories.)

NOTE: Do not store the FR2+ with the defibrillator pads attached. Do not open the pads package until ready for use.

With the battery installed and the FR2+ stored in appropriate environmental conditions, the FR2+ performs detailed periodic selftests to make sure that it remains ready for use. (See Appendix B for the environmental storage specifications.)

While the FR2+ is in the standby mode, the Status Indicator shows the flashing black hourglass unless the periodic selftests detect a problem. If a problem is detected, the Status Indicator will show a flashing red X or a solid red X and the FR2+ will beep ("chirp") to alert you to the need for troubleshooting. (See Chapter 4, "Maintaining, Testing, and Troubleshooting Your HeartStart FR2+," for instructions.)

Notes

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3 Using Your HeartStart FR2+

Overview

This chapter describes how to use the HeartStart FR2+ Defibrillator in an emergency incident. Some general things to remember are:

- Try to relax and stay calm. The FR2+ automatically provides appropriate voice and display prompts to guide you.
- The defibrillator pads must have good contact with the patient's skin. The pads have a layer of sticky, conductive gel beneath the protective backing. To work effectively, the gel must not be dried out.
- It may be necessary to dry the patient's skin or to clip or shave excessive chest hair to provide good contact between the defibrillator pads and the patient's skin.

The following pages provide step-by-step instructions for normal use of the FR2+ in an emergency. (See Chapter 4, "Maintaining, Testing, and Troubleshooting Your HeartStart FR2+," for troubleshooting tips.)

IMPORTANT: Be sure to read the Warnings and Cautions on the last page of this chapter.

NOTE: These directions apply to both the model M3860A and the model M3861A FR2+, except where otherwise noted.

3-2

Step 1: Preparation

Press the On/Off button to turn on the HeartStart FR2+ Defibrillator. Follow the instructions provided by the FR2+ voice and screen prompts in the order indicated.

Remove clothing from the patient's upper body. Wipe moisture from the patient's skin and clip or shave excessive chest hair, if necessary.
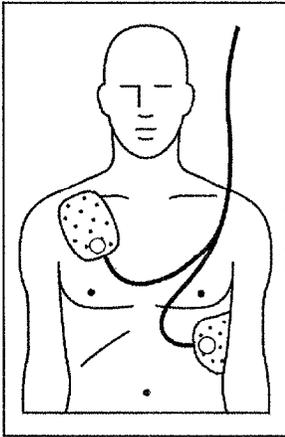
If the patient appears to be under eight years of age or 55 lbs (25 Kg), use M3870A FR2 infant/child reduced-energy defibrillator pads, if available. If the child appears older/larger, use adult defibrillator pads. DO NOT DELAY TREATMENT TO DETERMINE THE CHILD'S EXACT AGE/WEIGHT.

Open the defibrillator pads package. Check to see that the pads and attached cable and connector are undamaged. Pull off the protective backing from the defibrillator pads and check that the gel has not dried out. If the pads are damaged or the gel has dried out, use a new set of pads.

Place each pad on the patient. The pads must be placed with the sticky side on the patient's skin. **IMPORTANT: Refer to the drawing on each pad for correct positioning.** For adult patients, one pad goes just below the patient's right collarbone, and the other one goes over the patient's ribs in line with the armpit and below the left breast. For children under eight years old, one pad is centered on the chest between the nipples, and the other on the back between the scapulae (shoulder bones).
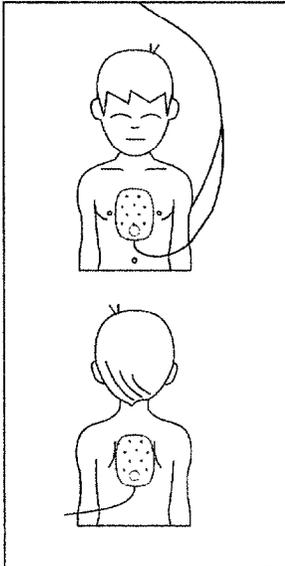
Connect the pads to the FR2+. Insert the defibrillator pads connector firmly into the connector socket. A flashing light shows you where the socket is located, at the top left of the FR2+.

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M3860A/M3861A HEARTSTART FR2+
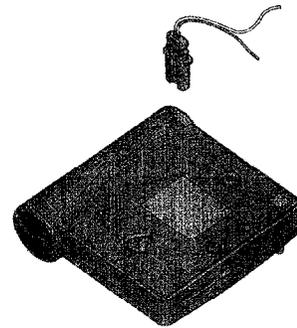
Step 2: ECG Analysis and Monitoring

Follow the instructions provided by the HeartStart FR2+ Defibrillator's voice and screen prompts in the order indicated.
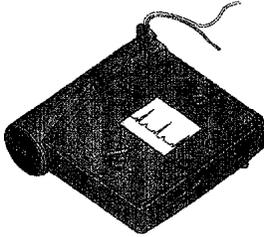
As soon as the FR2+ detects that the defibrillator pads are connected properly, it automatically begins analyzing the patient's heart rhythm. Do not touch the patient during rhythm analysis. The M3860A FR2+ can display the patient's ECG on the screen. When the ECG display is enabled, the patient's heart rate is also displayed during background monitoring and when the advanced mode is entered.

If no shock is advised, the FR2+ provides voice and screen prompts to tell you so. The FR2+ instructs you to perform CPR if needed, and performs background monitoring of the patient's ECG while you give appropriate care to the patient. These instructions are repeated at the programmed Monitor Prompt interval (the default interval is one minute) while the FR2+ is monitoring the patient.

NOTE: CPR may interfere with background monitoring. During CPR, periodically pause for 15 seconds to check the patient and allow the FR2+ to analyze the patient's heart rhythm without CPR artifact.

Monitoring continues until and unless the FR2+ detects a change in the patient's heart rhythm that may be a shockable rhythm, detects interference with rhythm analysis, or is turned off.

If the FR2+ detects a potentially shockable heart rhythm while monitoring, it automatically goes back to analyzing the rhythm to see if a shock is advised.

If a shock is advised, the FR2+ charges to prepare for shock delivery. It gives the voice warnings and screen prompts to tell you that a shock is advised. Make sure that no one is touching the patient or the pads. While the FR2+ is charging, it continues to analyze the patient's heart rhythm. If the rhythm changes and a shock is no longer appropriate, the FR2+ disarms. Voice and display prompts advise you what action to take.

NOTE: When the FR2+ is fully charged, you can disarm it at any time by pressing the On/Off button to turn off the FR2+ and return it to standby mode. (See the Defibrillator discussion in Appendix B, "Technical Specifications," for details on disarming the FR2+.)

Step 3: Shock Delivery

Press the Shock button to deliver the shock.

IMPORTANT: You must press the button for a shock to be delivered. *The HeartStart FR2+ Defibrillator will not automatically deliver a shock.*

There are four ways you can tell that the FR2+ is ready to deliver a shock:

- you hear a voice prompt telling you to deliver a shock,
- you see the Shock button flashing,
- you hear a steady tone, and/or
- you see a screen prompt telling you to press the orange (Shock) button.

After you press the Shock button, a voice prompt tells you the shock was delivered. Then FR2+ goes back to analyzing the patient's heart rhythm to see if the shock was successful. The FR2+ continues to provide voice and text prompts to guide you through additional shocks, if appropriate.

NOTE: If you do not press the Shock button within 30 seconds of being prompted, the FR2+ will disarm itself and provide a pause. The device will resume analyzing after 30 seconds or when the Resume Analyzing key is pressed.

Pause for CPR. After the programmed number of shocks in a shock series are delivered, the FR2+ automatically pauses for a programmed amount of time to allow you to perform CPR. After the voice and screen prompts tell you that the FR2+ has paused, there are no further voice prompts during the rest of the pause, so that you can provide uninterrupted patient care.

During the pause, the FR2+ screen shows a bar that fills in as the pause time is used up. The screen also shows how much time has gone by since the FR2+ was turned on,* and how many shocks have been delivered. The M3860A FR2+ also displays the ECG, if enabled, during this period.

* The FR2+ displays elapsed time to a maximum of 99:59 minutes. If the elapsed time of use extends beyond this figure, the minutes are represented by "??" but the seconds are displayed. However, total elapsed time will be recorded on an installed data card for later review with HeartStart Event Review data management software.

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ECG Display for Ongoing Observation

At the discretion of emergency care personnel, the M3860A FR2+ with ECG display enabled can also be used with the M3873A/M3874A FR2+ ECG assessment module. The FR2+ used with the FR2+ ECG assessment module provides a non-diagnostic ECG display of the patient's heart rhythm for attended patient monitoring. The system is intended for use on a conscious or breathing patient, regardless of age. While connected to the FR2+ ECG assessment module, the FR2+'s shock capability is disabled, but the FR2+ continues to evaluate the patient's ECG. The module is designed for connection to ECG electrodes per AAMI (M3873A) or IEC (M3874A) color convention.

There are no known contraindications to use of the FR2+ ECG assessment module.

The module's colored leadwires are connected to ECG electrodes, which are then placed on the patient's bare chest, and the module's device connector is inserted in the FR2+'s connector socket.

NOTE: It is not necessary to turn the FR2+ Defibrillator off prior to connecting the ECG assessment module.

Once connected, the FR2+ displays and evaluates the patient's ECG (Lead II). Follow all prompts from the FR2+. If a data card is used when the module is connected to the FR2+, all recorded events can be viewed using HeartStart Event Review data management software[*] on a personal computer.

Check the patient if:

- indicated by the observed ECG display,
- the patient becomes unresponsive or stops breathing, or
- the FR2+ prompts IF NEEDED, ATTACH DEFIBRILLATION PADS.

If appropriate, unplug the ECG assessment module from the FR2+, attach the defibrillator pads to the patient, and connect the defibrillator pads to the FR2+. *Verify that the defibrillator pads are at least one (1) inch (2.5 cm) away from the ECG electrodes.*

The M3873A/M3874A FR2+ ECG assessment module contains no latex rubber. It is reusable (see the expiration date on the module) and can be cleaned with a soft cloth dampened with any of the agents recommended for

[*] HeartStart Event Review software was previously sold as CodeRunner software.

cleaning the FR2+ Defibrillator. (See Chapter 4, "Maintaining, Testing, and Troubleshooting Your HeartStart FR2+.")

WARNING: During defibrillation, air pockets between the skin and defibrillator pads can cause patient skin burns. To help prevent air pockets, make sure defibrillator pads completely adhere to the skin. Do not use dried-out defibrillator pads.

WARNING: Do not let the defibrillator pads touch each other or other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may divert defibrillating current away from the heart.

WARNING: Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed diagnosis. If the FR2+ gives a SHOCK ADVISED prompt, keep the patient as still as possible for at least 15 seconds so the FR2+ can reconfirm the rhythm analysis before a shock is delivered.

WARNING: CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the FR2+.

WARNING: Defibrillation current can cause operator or bystander injury. Do not touch the patient during defibrillation. Do not allow the defibrillator pads to touch any metal surfaces. Disconnect the pads connector from the FR2+ before using any other defibrillator.

CAUTION: Aggressive handling of the pads in storage or prior to use can damage the pads. Discard the defibrillator pads if they become damaged.

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4 Maintaining, Testing, and Troubleshooting Your HeartStart FR2+

Overview

This chapter provides information on HeartStart FR2+ Defibrillator maintenance, detailed descriptions of the selftests, and a guide to troubleshooting.

Maintenance

Maintenance of the FR2+ is very simple, but it is a very important factor in its dependability. The FR2+ performs many maintenance activities itself. These include daily and weekly selftests to verify readiness for use and more detailed monthly selftests that also verify the shock waveform delivery system. In addition, a detailed selftest is run whenever a battery is installed in the FR2+.

The FR2+ requires no calibration or verification of energy delivery. The FR2+ has no user-serviceable parts.

CAUTION: Improper maintenance may damage the FR2+ or cause it to function improperly. Maintain the FR2+ only as described in this User's Guide or as designated by your program's Medical Director.

CAUTION: Electrical shock hazard. Dangerous high voltages and currents are present. Do not open the FR2+, remove its covers, or attempt repair. There are no user-serviceable components in the FR2+. The FR2+ should be returned to an authorized service center for repair.

The following table presents a schedule of suggested maintenance for the FR2+. Different frequency intervals may be appropriate, depending upon the environment in which the FR2+ is used. The required maintenance frequency is at the discretion of your program's Medical Director.

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daily	monthly	maintenance task/response
		Check the Status Indicator. If you see the flashing black hourglass: The FR2+ is ready to use. No action required. If you see anything other than a flashing black hourglass, remove and reinstall the battery to run the selftest. • If the selftest passes and the Status Indicator shows the flashing black hourglass, the FR2+ is ready to use. • If the selftest fails, install a new battery and run the selftest. If the selftest passes, the FR2+ is ready to use. If the selftest fails, contact Philips Medical Systems.
	✓	**Check supplies, accessories, and spares** for damage and expiration dating. Do not use damaged or expired accessories. Replace them immediately. If a LOW BATTERY or REPLACE BATTERY message is displayed: Replace the battery and run the selftests. DO NOT ATTEMPT TO CHARGE THE M3863A FR2 STANDARD BATTERY. It is not rechargeable. The M3848A FR2+ battery is rechargeable. Recharge it, using the M3849A Charger, for the FR2+ rechargeable battery only.
	✓	**Check the outside of the FR2+** and the connector socket for cracks or other signs of damage. If you see signs of damage: Contact Philips Medical Systems for technical support.

After Using the HeartStart FR2+

After each use of the FR2+, perform the maintenance tasks described in the table above, as well as the following post-use checks before returning the FR2+ to service:

- **Check the operation of the FR2+** by removing and reinstalling the battery and running the battery insertion selftest. **NOTE:** Perform also when replacing expired defibrillator pads.
- **Check the outside of the FR2+** and the connector socket for signs of dirt or contamination. If the FR2+ is dirty or contaminated, clean it according to the guidelines provided in this manual.
- **Check the data card** if one has been used. If the data card has been used to record incident data, remove and replace it with a blank data card. Deliver the recorded data card to appropriate personnel according to your local guidelines and medical protocol.

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- **Check the connector socket** to make sure that defibrillator pads or ECG Assessment Module are disconnected from the FR2+ when it is not in use.
- **Check to make sure the data card tray is installed,** even if a data card is not being used.

Cleaning the HeartStart FR2+

The outside of the FR2+, including the defibrillator pads connector socket, can be cleaned with a soft cloth dampened in one of several appropriate cleaning agents (see list below). The following guidelines include some important reminders:

- Do not immerse the FR2+ in fluids.
- Make sure a battery (or the M3864A training & administration pack) and a data card tray are installed when cleaning the FR2+, to keep fluids out of the device.
- Do not use abrasive materials, cleaners, strong solvents such as acetone or acetone-based cleaners, or enzymatic cleaners.
- Clean the FR2+ and the connector socket with a soft cloth dampened with one of the cleaning agents listed below.
  - Isopropyl alcohol (70% solution)
  - Soapy water
  - Chlorine bleach (30 ml/l water)
  - Ammonia-based cleaners
  - Glutaraldehyde-based cleaners
  - Hydrogen peroxide

CAUTION: Do not immerse any portion of the FR2+ in water or other fluids. Do not allow fluids to enter the FR2+. Avoid spilling any fluids on the FR2+ or accessories. Spilling fluids into the FR2+ may damage it or present a fire or shock hazard. Do not sterilize the FR2+ or accessories.

Operator's checklist

The checklist on the following page is for your reference. You may want to photocopy it or use it as the basis for creating your own checklist.

Inspect the FR2+ as suggested in the maintenance schedule above, or as specified by your Medical Director. When you use the Checklist, fill in the scheduled frequency intervals you will be using for your maintenance inspections.

Check off each requirement as you complete it, make a note of any problems you found or corrective action you took, and sign the form.

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OPERATOR'S CHECKLIST

HeartStart FR2+ Model No.: _____ Serial No.:_____

HeartStart FR2+ Location or Vehicle ID: _____

date							
scheduled frequency							
HeartStart FR2+ Clean, no dirt or contamination; no signs of damage							
Supplies Available • Two sets defibrillator pads, sealed, undamaged, within expiration date • Ancillary supplies (hand towel, scissors, razor, pocket mask, gloves) • Spare M3863A battery, within "Install Before" date • Data cards, undamaged, and spare data card tray							
Status Indicator Shows alternating hourglass/square; selftest passed.							
Inspected by Signature or initials of operator completing the maintenance inspection							
Remarks, Problems, Corrective Actions							

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Testing

The HeartStart FR2+ Defibrillator has several ways of testing itself and alerting you if it finds a problem. In addition to the selftest performed each time a battery is installed, the FR2+ also automatically performs periodic selftests daily.

NOTE: The FR2+ selftests are designed to check that the FR2+ is ready for use. However, in the event that the FR2+ has been dropped or mishandled, it is recommended that the battery be removed and reinstalled to initiate a selftest. If the FR2+ has visible signs of damage, contact Philips Medical Systems for technical support.

Battery insertion selftest

As described in Chapter 2, "Preparing Your HeartStart FR2+ for Use," when you insert the battery in the FR2+, be sure that neither the defibrillator pads nor the FR2+ ECG assessment module are connected to the device. When you insert the battery, a menu is displayed and a two-part selftest will run unless you make another selection from the menu within 10 seconds. The selftest includes an automatic part and an interactive part.

NOTE: Under certain circumstances, the behavior of your FR2+ will be different.
For example, the menu screen *will not* appear when a battery is inserted if:
- the defibrillator pads are attached to a patient, indicating that the FR2+ is in continued use,
- the FR2+ ECG assessment module is connected to the FR2+, or
- the battery is completely depleted.
The menu screen *will* be displayed, but after 10 seconds the FR2+ will go to standby mode if you make no selection and:
- less than five minutes have passed since the FR2+ was last used, indicating that the FR2+ is still in use.

It is recommended that the full selftest (including the interactive portion) be run under the following circumstances:

- When the FR2+ is first put into service and following each use.
- Whenever the battery is replaced.
- Whenever expired defibrillator pads are replaced during periodic maintenance.
- Whenever the defibrillator may have sustained physical damage.

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```
     RUN SELFTEST
   REVIEW INCIDENT
CARD FULL IN        XX.XH
    GOOD BATTERY
        NEXT
    IN EMERGENCY
  PRESS OFF TO QUIT
```

When you install the battery, the screen tells you whether or not a data card is installed. If so, a screen message displays how much recording time is left until the data card is full. (See Chapter 7, "Data Management and Review," for how to review the incident information from the internal memory of the FR2+ or from a data card, if one is used.)

NOTE: The data card is typically capable of storing a number of incidents. However, it is recommended that it be replaced after every use. In the unlikely event that the card fills up during an incident, no further data can be recorded, so it is important for you to monitor the CARD FULL IN... information on this screen.

Screen contrast can be adjusted during the battery insertion selftest by using the Option buttons.

```
     RUN SELFTEST
   REVIEW INCIDENT
   NO DATA CARD
   LOW BATTERY
        NEXT
    SELFTEST MUST
   PASS BEFORE USE
```

If battery power is low, replace the battery. If a previous selftest has failed, the screen displays a message that the FR2+ must pass a selftest before being used.

It is recommended that you always have a spare battery available. However, if a screen display prompts you to replace the battery or the Status Indicator shows a flashing red **X**, but you do not have a spare battery, you can continue to use the FR2+ until the battery is completely depleted. This may be necessary in an emergency.

NOTE: It is recommended that the M3848A FR2+ rechargeable battery not be used as a spare or backup battery.

NOTE: If you connect defibrillator pads (that are applied to the patient) or the FR2+ ECG assessment module to the FR2+ during a battery insertion selftest, the selftest will stop and the FR2+ will go to its standby mode to be ready for use.

During the automatic part of the selftest, the screen displays a bar that fills in as the test continues. When that part of the test is finished, the FR2+ beeps. The results of the selftest are automatically recorded on the data card while the tests are running, if a data card was inserted in the FR2+ prior to installing the battery.

If the automatic part of the selftest fails:

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```
┌──────────────────────────┐
│                          │
│    SELFTEST FAILED       │
│ REV:     XXX X.X XXXX     │
│                          │
│    NOT READY FOR USE      │
│    SN 000000001          │
│    SERVICE REQUIRED       │
└──────────────────────────┘
```

```
┌──────────────────────────┐
│    SELFTEST PASSED        │
│ REV:     XXX X.X XXXX     │
│    NO DATA CARD           │
│                          │
│    SN 000000001          │
├──────────────────────────┤
│    IN EMERGENCY          │
│    PRESS OFF TO QUIT      │
└──────────────────────────┘
```

- The screen displays a message that the selftest has failed. After a short time, an error code is displayed. Write down the error code and contact Philips Medical Systems for technical support.
- The Status Indicator shows a flashing or solid red **X**.

Replace the battery with a new battery and repeat the test. If the second selftest fails, contact Philips Medical Systems for technical support.

If the automatic part of the selftest passes:

- The screen displays a message that the selftest passed, then begins the interactive part of the test.

The interactive part of the selftest requires you to respond to prompts in order to make sure the display, buttons, lights, and speaker on the FR2+ are working properly.

Screen prompts guide you through a series of steps in the interactive part of the selftest. Some ask you to observe that a feature of the FR2+ works properly. Others ask you to take certain actions – for example, to press a button. The screen then displays a message showing that the button's operation has been verified. If you do not press the button, or if you do but the button is not working, the screen displays a message that the button's function is not verified.
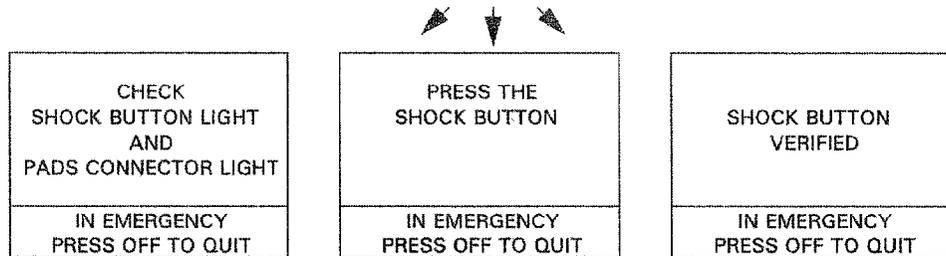
```
┌────────────────────┐  ┌────────────────────┐  ┌────────────────────┐
│      CHECK         │  │    PRESS THE       │  │   SHOCK BUTTON     │
│ SHOCK BUTTON LIGHT │  │   SHOCK BUTTON     │  │    VERIFIED        │
│       AND          │  │                    │  │                    │
│ PADS CONNECTOR LIGHT│ │                    │  │                    │
├────────────────────┤  ├────────────────────┤  ├────────────────────┤
│   IN EMERGENCY     │  │   IN EMERGENCY     │  │   IN EMERGENCY     │
│  PRESS OFF TO QUIT │  │  PRESS OFF TO QUIT │  │  PRESS OFF TO QUIT │
└────────────────────┘  └────────────────────┘  └────────────────────┘
```

It is important to press the buttons and verify the indicators to ensure that the FR2+ will be ready for use. If something does not work correctly – for example, if lights do not come on or you do not hear beeps when expected – make a note of the problem and contact Philips Medical Systems for technical support.

NOTE: Do not use the FR2+ until *all* parts of the interactive selftest verify correct performance. Be sure to note and report any problems you find.

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The following table describes the parts of the FR2+ tested in the interactive part of the selftest and any action you are asked to take.

feature	test description
speaker	Screen prompt: CHECK SPEAKER SOUND (2 beeps) > Listen for the two beeps from the speaker.
lights	Screen prompt: CHECK SHOCK BUTTON LIGHT AND PADS CONNECTOR LIGHT > Check that the lights come on.
option buttons	Screen prompt: PRESS THE OPTION BUTTONS > Press the blue upper and lower Option buttons and listen for a beep to confirm each press. Look at the screen to be sure the button presses have been verified.
display screen	Screen prompt: CHECK DISPLAY. ADJUST CONTRAST IF NEEDED > Check the test pattern displayed on the screen. Adjust the contrast if desired using the Option buttons. NOTE: Screen contrast can be adjusted at any time during the interactive selftest by repeatedly pressing the appropriate Option button until desired contrast is achieved.
shock button	Screen prompt: PRESS THE SHOCK BUTTON > Press the Shock button and listen for a beep to confirm the press. No shock will be delivered when you press the Shock button during the test. > Look at the screen to be sure the button press has been verified.
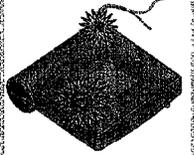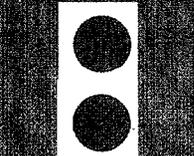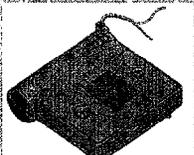
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feature	test description
on/off button	Screen prompt: **PRESS THE ON/OFF BUTTON** > Press the On/Off button and listen for a beep to confirm press. > Look at the screen to be sure the button press has been verified. The screen then displays a message that the test is complete.

When the interactive part of the battery insertion selftest is complete, the FR2+ turns off and goes to standby mode to be ready for use.

If proper operation of all features has not been verified in the interactive selftest, you may want to rerun the battery insertion selftest. If a feature of operation cannot be verified, contact Philips Medical Systems for technical support.

Periodic selftests

In addition to the battery insertion selftest, the FR2+ automatically performs periodic selftests (PSTs). These daily, weekly, and extensive monthly selftests check many important functions of the FR2+, including battery capacity and internal circuitry.

If it detects a problem during one of these periodic selftests, the FR2+ beeps and displays a flashing red **X** or a solid red **X** on the Status Indicator.

Device history

```
DEVICE HISTORY
BATTERY HISTORY
     SETUP
     CLOCK
    RETURN
  IN EMERGENCY
PRESS OFF TO QUIT
```

The FR2+ stores key information about its history in internal memory. To review the history of your FR2+, select NEXT from the menu screen displayed when you insert the battery, then select DEVICE HISTORY from the next menu displayed.

The device history information is read from the internal memory of the FR2+. It includes:

```
DEVICE HISTORY
     RETURN
USES:      12   19
SHOCKS:         17
TRAINING:  25  456
TESTS:    156   22
          510   95
REV:    01E 1.5 ABA1
```

- **USES** – how many times the FR2+ has been used (shown in the left column of numbers) and the total time in minutes it has been used (shown in the right column of numbers);
- **SHOCKS** – the total number of shocks it has delivered;
- **TRAINING** – how many times it has been used with the training & administration pack for training (left column) and the total time in minutes it has been used for training (right column); and

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```
DEVICE HISTORY
BATTERY HISTORY
     SETUP
     CLOCK
     RETURN
  IN EMERGENCY
PRESS OFF TO QUIT
```

- **TESTS** – how many tests have been run. Four figures are shown: daily (upper left), weekly (upper right), and monthly (lower left) periodic selftests, and battery insertion selftests (lower right).
- **REV** – device language, model, and software revision.

Battery History

Information about use of the battery currently installed in your FR2+ is also available. To review the history of the battery, select NEXT from the menu screen displayed when you insert the battery, then select BATTERY HISTORY from the next menu displayed.

The battery history information is read from the internal memory of the battery. It includes:

```
    BATTERY HISTORY
        RETURN
USE MINUTES:        519
CHARGES:             40
     GOOD BATTERY
STATUS:        00000000
```

- **USE MINUTES** – the total operating time (in minutes), including selftest time, for this battery;
- **CHARGES** – the total number of full defibrillation charges that have been provided by this battery, including selftest charges;
- **BATTERY** – a GOOD BATTERY (M3863A) or a fuel gauge display (M3848A) showing 25%, 50%, 75% or 100%, or a LOW BATTERY or REPLACE BATTERY message, as appropriate.
- **STATUS** – the current status of this battery, displayed in a binary code. Make a note of this code if technical service is needed.

```
    BATTERY HISTORY
        RETURN
USE MINUTES:        519
CHARGES:             40
  0% ███████ 100%
STATUS:        00000000
```

Troubleshooting Guide

Status indicator summary

status indicator	meaning
	The FR2+ passed the battery insertion self-test or the last periodic self-test and is therefore ready for use.
Flashing red X accompanied by a chirping sound.	A self-test error has occurred or the battery is low or depleted.
	The battery is completely depleted or a self-test failure occurred.

NOTE: Perform CPR (if needed) any time there is a delay before the FR2+ can be used.

Recommended action during an emergency

If the status indicator displays the flashing black hourglass, follow all voice and screen prompts.

The HeartStart FR2+ Defibrillator is designed to continue working even if the status indicator displays a flashing red X, although the device may not perform to all of its specifications. Voice and text prompts should be followed whenever they are given. If for any reason you cannot hear voice prompts during use of the defibrillator, periodically check the device screen for text prompts.

NOTE: After completing emergency use of the FR2+, if you are unable to clear the problem as described in this Troubleshooting section, and the Status Indicator does not show the flashing black hourglass, contact Philips Medical Systems for technical support.

In the unlikely event that the device becomes unresponsive during use:

1. cycle power (press the On/Off button once, wait one second, then press it again), or

2. remove and reinstall the battery (use a new M3863A FR2 standard battery, if available, or a charged M3848A FR2+ rechargeable battery).

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If neither of these actions clears the problem, do not use the FR2+. Attend to the patient, providing CPR if needed, until emergency medical personnel arrive.

Troubleshooting during patient use

symptom	possible cause	recommended action
STATUS INDICATOR: FLASHING RED X		
screen and voice prompts:	• The energy remaining in the battery is low.	Install fully charged battery.
	• The energy in the battery is nearly depleted. The FR2+ will turn off if a new battery is not installed.	
STATUS INDICATOR: FLASHING BLACK HOURGLASS		
Screen and voice prompts: **APPLY PADS AND PRESS PADS FIRMLY** or **PLUG IN CONNECTOR** Or voice prompts: **INSERT CONNECTOR FIRMLY** or **PRESS PADS FIRMLY TO PATIENT'S BARE CHEST** or **POOR PADS CONTACT**	The defibrillator pads: • are not properly applied to the patient, or • are not making good contact with the patient's bare chest because of moisture or excessive hair, or • are touching each other. The defibrillator pads connector: • is not firmly inserted in the connector socket.	• Make sure that the defibrillator pads are sticking completely to the patient's skin. • If the pads are not sticking, dry the patient's chest and shave or clip any excessive chest hair. • Reposition the pads. • Make sure the pads connector is completely inserted in the connector socket. If the prompt continues after you do these things, replace the pads.
voice and screen prompts: **REPLACE PADS**	• The defibrillator pads, cable, or connector may be damaged. • The FR2+ has detected a possible problem with the defibrillator pads or pads cable.	Replacing defibrillator pads may permit device to operate.

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symptom	possible cause	recommended action
Voice prompts: ANALYZING INTERRUPTED or CANNOT ANALYZE or STOP ALL MOTION	• The patient is being moved or jostled. • Radio or electrical sources are interfering with ECG analysis. • The environment is dry and movement around the patient is causing static electricity to interfere with ECG analysis.	• Stop CPR, do not touch the patient. Minimize patient motion. If the patient is being transported, stop the vehicle if needed. • Check for possible causes of radio and electrical interference and remove them from the area. • Responders and bystanders should minimize motion, particularly in dry environments that can generate static electricity.
Voice prompt: NO SHOCK DELIVERED	The patient impedance is not appropriate for the FR2+ to deliver a shock.	
Voice prompt: SHOCK BUTTON NOT PRESSED	Shock has been advised but not delivered within 30 seconds. (FR2+ has been disarmed.)	• When next prompted, press the Shock button to deliver shock.

General troubleshooting

symptom	possible cause	recommended action
	• The energy remaining in the battery is low. • The FR2+ has been stored outside the recommended temperature range. • An error has been detected as part of the self-test. • The FR2+ has been unable to perform its daily self-tests.	
Status Indicator: FLASHING OR SOLID RED X Audio signal: CHIRPING Screen prompt (displayed for 10 seconds at the end of a BIT before FR2+ turns off): NOT READY FOR USE or SELFTEST FAILED	A test revealed a failure or error. The FR2+ performs self-tests every time it is turned on, when a battery is inserted, and periodically while it is in standby mode.	• Unplug the pads connector from the FR2+, if connected. • Remove and reinstall the battery, and check the results of the battery insertion self-test. If it fails, install a new M3863A FR2 standard battery or a charged M3848A FR2+ rechargeable battery and repeat the test. If it fails again, do not use the FR2+. *NOTE: You can stop the tests and use the FR2+ as soon as you see the Status Indicator change to the flashing black hourglass. Simply press the On/Off button to stop the test and put the FR2+ into standby mode. The FR2+ is then ready for use.*

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symptom	possible cause	recommended action
	• The battery is missing or completely depleted. • The training & administration pack is being used in the administration function (the solid red X is normal in this case) or has been left in the FR2+ by mistake. • A self test detected a failure.	
Status indicator: SOLID RED X Audio signal: CHIRPING	• The training & administration pack is being used in the ADMINISTRATION function and more than 10 minutes have passed without user interaction (button press or pads change). • The training & administration pack is being used in the TRAINING function and more than 30 minutes have passed without user interaction (button press or pads change).	• To continue using the training & administration pack, press any button (except On/Off). • To return the FR2+ to standby mode, remove the Pack and install a battery.
Status indicator: NONE	The FR2+ has been physically damaged.	

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Notes

M3860A/M3861A HEARTSTART FR2+

5 Clinical and Safety Considerations

Clinical Considerations

Indications

The HeartStart FR2+ is indicated for use on victims of sudden cardiac arrest exhibiting the following signs:

- Unresponsiveness
- Absence of normal breathing

The HeartStart FR2+ is intended for use by personnel who have been trained in its operation. The user should be qualified by training in basic life support, advanced life support, or other physician-authorized emergency medical response.

NOTE: At the discretion of emergency care personnel, the M3860A FR2+ with ECG display enabled can also be used with the FR2+ ECG assessment module to display the rhythm of a responsive or breathing patient, regardless of age. There are no known contraindications to use of the FR2+ ECG assessment module.

Contraindications

The HeartStart FR2+ is contraindicated for use (should *not* be used) on patients who show either of the following signs:

- Responsiveness
- Presence of normal breathing

Safety Considerations

You should be aware of the safety concerns listed here when you use the HeartStart FR2+. Read them carefully. You will also see some of these messages in other parts of this manual. The messages are labeled Danger, Warning, or Caution.

- **DANGER**– immediate hazards that will result in personal injury or death.
- **WARNING**– conditions, hazards, or unsafe practices that can result in serious personal injury or death.

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- **CAUTION** – conditions, hazards, or unsafe practices that can result in minor personal injury, damage to the HeartStart FR2+, or loss of data stored in the device.

THESE SAFETY CONSIDERATIONS ARE DIVIDED INTO FOUR GROUPS: SAFETY CONCERNS ABOUT THE HEARTSTART FR2+ IN GENERAL USE, DEFIBRILLATION, MONITORING, AND MAINTENANCE ACTIVITIES.

The dangers, warnings, and cautions listed in the following tables apply to both the model M3860A and the model M3861A HeartStart FR2+, unless otherwise noted.

General dangers, warnings, and cautions

safety level	possible shock or fire hazard, or explosion
DANGER	THERE IS A POSSIBILITY OF EXPLOSION IF THE HEARTSTART FR2+ IS USED IN THE PRESENCE OF FLAMMABLE ANESTHETICS OR CONCENTRATED OXYGEN.
DANGER	THE HEARTSTART FR2+ HAS NOT BEEN EVALUATED OR APPROVED FOR USE IN HAZARDOUS LOCATIONS AS DEFINED IN THE NATIONAL ELECTRICAL CODE (ARTICLES 500-503). IN ACCORDANCE WITH THE IEC CLASSIFICATIONS (SECTION 5.5.), THE HEARTSTART FR2+ IS NOT TO BE USED IN THE PRESENCE OF FLAMMABLE SUBSTANCE/AIR MIXTURES.
DANGER	DO NOT RECHARGE THE M3863A FR2 STANDARD BATTERY.
WARNING	Use the HeartStart FR2+ only as described in this manual. Improper use of the HeartStart FR2+ can cause death or injury. Do not press the Shock button if the defibrillator pads are touching each other or are open and exposed.
CAUTION	Hazardous electrical output. The HeartStart FR2+ is for use only by qualified personnel.
CAUTION	Do not immerse any portion of the HeartStart FR2+ in water or other fluids. Do not allow fluids to enter the HeartStart FR2+. Avoid spilling any fluids on the HeartStart FR2+ or accessories. Spilling fluids into the HeartStart FR2+ may damage it or present a fire or shock hazard. Do not sterilize the HeartStart FR2+ or accessories.

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safety level	possible improper device performance
WARNING	Prolonged or aggressive CPR to a patient with defibrillator pads attached can damage the pads. Replace the defibrillator pads if they are damaged during use or handling.
WARNING	Using damaged or expired equipment or accessories may cause the HeartStart FR2+ to perform improperly, and/or injure the patient or the user.
WARNING	CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the HeartStart FR2+.
WARNING	Poor electrode pad-to-patient contact may result in a related defibrillator prompt or other indication. Check all electrical and patient connections.
CAUTION	The HeartStart FR2+ is designed to be used only with Philips-approved accessories. The HeartStart FR2+ may perform improperly if non-approved accessories are used.
CAUTION	Follow all instructions supplied with the HeartStart defibrillator pads. Use the defibrillator pads before the expiration date shown on the package. Do not reuse the defibrillator pads. Discard them after use.
CAUTION	Aggressive handling of the defibrillator pads in storage or prior to use can damage the pads. Discard the defibrillator pads if they become damaged.
CAUTION	Follow all instructions supplied with the M3863A FR2 standard battery. Install the battery before the expiration date shown on the battery.
CAUTION	Follow all instructions supplied with the M3848A FR2+ rechargeable battery. Recharge using the M3849A charger only.
CAUTION	Do not use the M3849A charger on aircraft.
CAUTION	The HeartStart FR2+ was designed to be sturdy and reliable for many different field use conditions. However, excessively rough handling can result in damage to the HeartStart FR2+ or its accessories. Inspect the unit and accessories periodically according to instructions.
CAUTION	Alteration of the factory default setup of the FR2+ can affect its performance and should be performed under the authorization of your Medical Director. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

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Clinical and Safety Considerations

safety level	possible improper device performance
CAUTION	Use only Philips-approved data cards. The HeartStart FR2+ may perform improperly if non-approved accessories are used.

safety level	possible electrical interference with ECG monitoring
WARNING	Radio-frequency (RF) interference from devices such as cellular phones and two-way radios can cause improper HeartStart FR2+ operation. The HeartStart FR2+ should be used at least 6 feet (2 meters) away from RF devices, as stated in accordance with EN 61000-4-3:1996.

Defibrillation warnings and cautions

safety level	possible shock hazard
WARNING	Defibrillation current can cause operator or bystander injury. Do not touch the patient during defibrillation. Disconnect the pads connector from the HeartStart FR2+ before using any other defibrillator.

safety levels	possible ECG misinterpretation
WARNING	For safety reasons, some very low-amplitude or low-frequency heart rhythms may not be interpreted by the HeartStart FR2+ as shockable VF rhythms. Also, some VT rhythms may not be interpreted as shockable rhythms.
WARNING	Handling or transporting the patient during heart rhythm analysis can cause an incorrect or delayed diagnosis. If the HeartStart FR2+ gives a SHOCK ADVISED prompt, keep the patient as still as possible for at least 15 seconds so the HeartStart FR2+ can reconfirm the rhythm analysis before a shock is delivered.

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safety levels	possible burns and ineffective energy
WARNING	Do not allow the defibrillator pads to touch each other or other ECG electrodes, lead wires, dressings, transdermal patches, etc. Such contact can cause electrical arcing and patient skin burns during defibrillation and may also divert the defibrillation current away from the heart.
WARNING	During defibrillation, air pockets between the skin and defibrillator pads can cause patient skin burns. To help prevent air pockets, make sure defibrillator pads completely adhere to the skin. Do not use dried out defibrillator pads.

safety level	possible patient injury
CAUTION	The HeartStart FR2+ advanced mode's MANUAL CHARGE feature is intended for use only by authorized operators who have been specifically trained in cardiac rhythm recognition and in defibrillation therapy using manual charge and shock delivery.

Monitoring cautions

safety level	possible misinterpretation of ECG recordings
CAUTION	The LCD screen on the HeartStart FR2+ model M3860A is intended only for basic ECG rhythm identification. The frequency response of the monitor screen is not intended to provide the resolution needed for diagnostic and ST segment interpretation.

Maintenance cautions

safety level	possible fire or shock hazard
CAUTION	Electrical shock hazard. Dangerous high voltages and currents are present. Do not open the HeartStart FR2+, remove its covers, or attempt repair. There are no user-serviceable components in the HeartStart FR2+. The HeartStart FR2+ should be returned to an authorized service center for repair.

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safety level	possible fire or shock hazard
CAUTION	Improper maintenance may damage the HeartStart FR2+ or cause it to function improperly. Maintain the HeartStart FR2+ only as described in this User's Guide or as designated by your program's Medical Director.

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6   Setup and Advanced Mode Features

Setup Overview

The "setup" of the HeartStart FR2+ Defibrillator is made up of several programmable aspects, or parameters, of FR2+ operation. Some setup parameters govern specific features that are not related to the patient care protocol, some are used to define the automatic patient care protocol used by the FR2+, and some provide options for manual override of the protocol during use.

The FR2+ comes with a factory default setup designed to meet the needs of most users. If desired, your Medical Director can revise the setup. Even if no changes are made, however, it is a good idea to understand the setup of your FR2+ and how the different parameter settings affect the way the device works.

Non-protocol parameters

The parameters listed in the following table enable features of FR2+ operation that are not related to the patient treatment protocol. The table describes each of these non-protocol parameters, lists the settings available for it, and identifies the default setting.

parameter	settings	default	description
speaker volume	1, 2, 3, 4, 5, 6, 7, 8	6	Sets volume of the FR2+'s speaker. 1 is lowest; 8 highest. The speaker is used for voice prompts and the charge-done tone.
record voice	YES, NO	NO	Enables or disables the audio recording during incident. Voice recording requires use of a data card.
ECG display (M3860/861 V)	ON, OFF	ON	Enables (ON) or disables (OFF) ECG display on the screen. FR2+ rhythm analysis does not require ECG display to be on. (ECG display cannot be changed from default OFF for M3861 A.)
autosend PST	ON, OFF	OFF	Enables (ON) or disables (OFF) transmission of the results of the FR2+'s periodic selftests (PST) from its infrared communications port.

Automatic protocol parameters

The HeartStart FR2+ is designed to follow an automatic protocol that guides you through patient treatment with the defibrillator. The default settings for programmable parameters used in the automatic protocol can be altered by your Medical Director if desired.

The setup parameters in the following table are used to define the automatic patient care protocol used by the FR2+. Many of these parameters interact with each other, so it is very important to understand how each parameter affects the protocol. The description of each parameter identifies any interacting parameters in **boldface type**.

parameter	settings	default	description
	1, 2, 3, 4		Sets the number of shocks that must be delivered to activate an automatic CPR pause. The length of the CPR pause after completion of a Shock Series is defined by the **CPR Timer** setting. A new Shock Series begins when a shock is delivered: • after the FR2+ is turned on, • after the automatic CPR pause, or • after the **Pause Key** (if enabled) has been pressed, or • if the time since the previous shock exceeds the **Protocol Timeout** setting.
protocol timeout (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, ∞ (infinite)	1.0	Sets the time interval used to determine if a delivered shock should be counted as part of the current **Shock Series**.
CPR timer (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0		Sets the length of the CPR pause period* that automatically starts when: • a Shock Series is completed, or • the **Pause Key** (if enabled) is pressed, or • a No Shock Advised (NSA) decision is made, the NSA CPR pause is enabled, and the conditions for using the CPR Timer setting for the NSA CPR pause period are met (see **NSA Action**). After the CPR pause, the FR2+ returns to automatic rhythm analysis. *The CPR pause period is lengthened by 10 seconds to allow time for initial voice prompting.

parameter	settings	default	description
NSA action (minutes)	MONITOR, 0.5, 1.0, 1.5, 2.0, 2.5, 3.0	MONITOR	Sets how the FR2+ behaves following a NO SHOCK ADVISED (NSA) decision: MONITOR – directs the FR2+ to monitor the patient's ECG following an NSA decision and to prompt the user periodically to provide CPR. The interval for CPR prompting is set by the **Monitor Prompt Interval**. TIME SETTING – directs the FR2+ to provide a CPR pause period following an NSA decision (NSA CPR Pause). • If no shocks have been delivered in the current Shock Series (e.g., the patient's initial monitored rhythm is non-shockable), the length of the CPR pause is defined by the **NSA Action** time setting. • If shocks have been delivered in the current **Shock Series** (e.g., the NSA decision follows a shock), the length of the CPR pause is instead defined by the **CPR Timer** setting.
CPR prompt	LONG, SHORT	LONG	Sets the level of detail provided in the CPR reminder voice prompts provided at the completion of a **Shock Series**. LONG – provides detailed coaching to check airway, breathing, and pulse before beginning CPR. SHORT – simply directs user to begin CPR if needed.
monitor prompt interval (minutes)	1.0, 1.5, 2.0, 2.5, 3.0, ∞ (infinite)	1.0	Sets the interval for patient care prompts provided during FR2+ monitoring of the patient's ECG following an NSA decision. Selection of ∞ (infinite) means that no repeat prompting will be provided during ECG monitoring.

Manual override parameters

The HeartStart FR2+ provides several ways of overriding the automatic protocol. The parameters in the following table are used to enable different kinds of manual override.

parameter	settings	default	description
	OFF, ANALYZE, CHARGE		Enables or disables advanced mode entry for ALS or tiered response systems. OFF — disables advanced mode features. ANALYZE — enables user-initiated rhythm analysis and disarm, and (M3860A only) automatically turns on ECG display when advance mode is entered. CHARGE (M3860A only) — in addition to enabling the analyze feature, enables user-initiated charging and disarming.
pause key	OFF, MONITOR, ALWAYS	OFF	Enables or disables user-initiated CPR pause in the automatic protocol. The length of the pause is defined by the **CPR Timer** setting. When an **Advanced** mode feature (ANALYZE or CHARGE) is enabled and accessed, the Pause key is disabled.

OFF – disables availability of user-initiated pause.

MONITOR – enables user-initiated pause only during FR2+ monitoring of patient rhythm.

ALWAYS – enables user-initiated pause any time except when the device is already paused.

```
MONITORING
ATTEND TO PATIENT



0:43      2⌇     HR XXX
    PAUSE FOR CPR>
```

If enabled, the Pause Key is accessed by pressing the lower Option button indicated by an arrow on the FR2+ display, as shown in the sample screen:

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parameter	settings	default	description
	ON, OFF		Enables (ON) or disables (OFF) user-initiated interruption of the CPR pause and return to analyzing. If either the **CPR Timer** or the **NSA Action** setting is programmed to 1.5 minutes or longer, the Resume Key setting is automatically enabled (ON). If enabled, the Resume Key is accessed by pressing the lower Option button indicated by an arrow on the FR2+ display, as shown in the sample screen.
advanced use prompt interval (minutes)	0.5, 1.0, 1.5, 2.0, 2.5, 3.0	0.5	Sets the interval for "Press to Analyze" prompts provided during advanced mode operation.
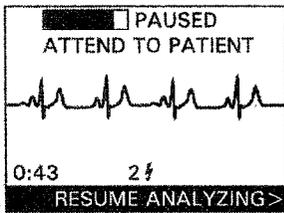
Sample screen:

☐ PAUSED
ATTEND TO PATIENT

0:43   2⚡
RESUME ANALYZING>

Using Setup Features

NOTE: To move around the menus displayed, use the Option buttons as follows:
- Press the LOWER Option button to move the highlight bar from one item to another on the menu.
- Press the UPPER Option button to select the highlighted item or to scroll through the settings for that item.

The FR2+ comes with a factory default setup designed to meet the needs of most users. The setup feature of the FR2+ lets you review the current setup of your HeartStart FR2+ or install a revised setup if appropriate. To go to the SETUP menu:

1. Remove and reinstall the battery to bring up the first menu on the screen.

   NOTE: This screen will *not* be displayed if the FR2+ is connected to defibrillator pads (that are applied to the patient) when the battery is inserted, and you will not be able to access the menu items. In addition, the battery insertion selftest and periodic automatic selftests cannot run while the defibrillator pads are connected. *Be sure to unplug the pads connector from the FR2+ after each use. Do not store the FR2+ with the pads connected.*

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```
RUN SELFTEST
REVIEW INCIDENT
NO DATA CARD
GOOD BATTERY
NEXT
IN EMERGENCY
PRESS OFF TO QUIT
```

```
DEVICE HISTORY
BATTERY HISTORY
SETUP
CLOCK
RETURN
IN EMERGENCY
PRESS OFF TO QUIT
```

```
SETUP
RETURN
RECEIVE SETUP
READ SETUP
REVIEW SETUP
```

2. Within 10 seconds of installing the battery, press the lower Option button to move the highlight bar to NEXT.

3. Press the upper Option button to select NEXT.

4. Press the lower Option button to move the highlight bar to SETUP.

5. Press the upper Option button to bring up the SETUP menu.

The SETUP menu allows you to receive setup directly from another HeartStart FR2+ or a computer running HeartStart Event Review software, read setup from a data card, or review current setup.

Reviewing current setup

A good way to understand the setup of your FR2+ is to review the setup it currently uses.

1. Select REVIEW SETUP from the SETUP menu. The first of a series of REVIEW SETUP screens is displayed.

2. After reviewing the screen contents, press the upper Option button to select NEXT and move to the next screen.

3. The last screen allows you to select RETURN and go back to the SETUP menu.

REVIEW SETUP	
NEXT	
SPEAKER VOLUME	8
RECORD VOICE	NO
ECG DISPLAY	ON
AUTOSEND PST	OFF
ECG OUT	OFF

REVIEW SETUP	
NEXT	
SHOCK SERIES	3
PROTOCOL TIMEOUT	1.0
PAUSE KEY	MONITOR
RESUME KEY	OFF
CPR TIMER	1.0
NSA ACTION	MONITOR

REVIEW SETUP	
RETURN	
ADVANCED	OFF
CPR PROMPT	LONG
PROMPT INTERVALS	
MONITOR	1.0
ADVANCED USE	0.5

Revising setup

There are several ways to change the setup of your HeartStart FR2+. All of them require use of products or accessories available separately from Philips Medical Systems.

- Use the M3864A training & administration pack to enable software within the FR2+ to modify its setup. (Instructions are provided with the Pack.)

- Read a revised setup from a data card containing the setup. (Instructions are provided later in this chapter.)

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- Use the infrared communications feature of the FR2+ to receive the revised setup from another FR2+. (Instructions are provided later in this chapter.)

- Use the infrared communications feature of the FR2+ to receive the revised setup from a computer running HeartStart Event Review software. (Instructions are provided with the HeartStart Event Review software.)

CAUTION: Alteration of the factory default setup of the FR2+ can affect its performance and should be performed under the authorization of your Medical Director. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

See the tables describing the various setup parameters at the beginning of this chapter and Appendix D, "Glossary of Terms," for definitions of setup items.

Receiving setup

This method uses the infrared communications feature of the HeartStart FR2+ to receive setup directly from one HeartStart FR2+ to another (which must have the training & administration pack installed in it) or from a computer running HeartStart Event Review software. (See instructions provided with HeartStart Event Review.) To receive setup from another FR2+, follow these steps:

1. Locate the infrared communications port on each HeartStart FR2+ and line them up with one another, so that the infrared "eye" in each one has an uninterrupted view of the "eye" in the other. (See the diagram on the inside front cover.) The two devices should be no more than 1 meter apart.

SETUP
RETURN
RECEIVE SETUP
READ SETUP
REVIEW SETUP

2. Make sure the "sending" FR2+ has the training & administration pack installed and is ready to send. (See the M3864A training & administration pack *Reference Guide* for instructions.)

3. Select RECEIVE SETUP from the setup menu:

4. A new screen comes up. Until the two HeartStart FR2+ devices are properly positioned, the screen displays READY TO RECEIVE and prompts you to check the sending FR2+.

RECEIVE SETUP
EXIT
READY TO RECEIVE
CHECK SENDER

5. Setup data are automatically transferred as soon as the infrared ports are correctly aligned.

6. If you select EXIT before the transfer is complete, the revised setup will *not* be received. When the transfer is complete, the screen on the

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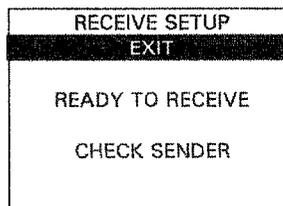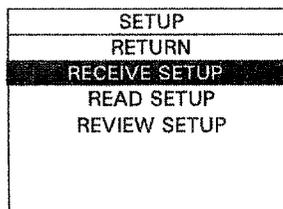
Setup and Advanced Mode Features

"receiving" FR2+ displays a SETUP COMPLETE message. Your HeartStart FR2+ immediately uses the new setup.

Receiving setup from a computer running HeartStart Event Review software is discussed in the directions for use provided with HeartStart Event Review software.
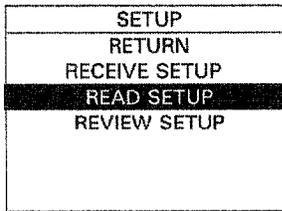
Reading setup

This method copies setup data from a data card to your HeartStart FR2+. To read the setup, follow these steps:

SETUP
RETURN
RECEIVE SETUP
READ SETUP
REVIEW SETUP

1. Insert the data card in the data card tray and install the loaded tray into the data card slot in the FR2+.

2. Select READ SETUP from the setup menu.

3. A new screen comes up. If the FR2+ cannot read the data card or cannot find a valid setup on the data card, the screen displays a NO SETUP FILE error message. Otherwise, the FR2+ begins reading the setup information from the data card immediately.

READ SETUP
EXIT
⚠
NO SETUP FILE

4. If you select EXIT before the transfer is complete, the revised setup will *not* be copied. When the transfer is finished, the screen displays a SETUP COMPLETE message. Your FR2+ immediately uses the revised setup.
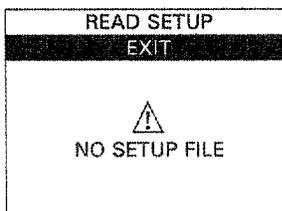
Sending and Receiving Clock Settings

To synchronize the clock settings of your HeartStart FR2+ with the clock of another FR2+ or a computer running HeartStart Event Review software, you can use the infrared communications feature.

RUN SELFTEST
REVIEW INCIDENT
NO DATA CARD
GOOD BATTERY
NEXT
IN EMERGENCY
PRESS OFF TO QUIT

Instructions for synchronizing clock settings using a computer running HeartStart Event Review are provided with the HeartStart Event Review software.

To transfer clock settings from one FR2+ to another:

1. Remove and reinstall the battery of both FR2+ devices to bring up the first menu screen.

2. Select NEXT to go to the second menu screen.

CLOCK
RETURN
RECEIVE TIME
SEND TIME
07 / 09 / 00
DD / MM / YY
14 : 28

3. Select CLOCK from the second menu screen. The CLOCK screen then comes up.

4. Locate the infrared communications port on each FR2+ and line them up with one another, so that the infrared "eye" in each one has an

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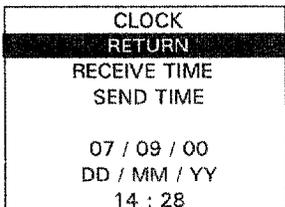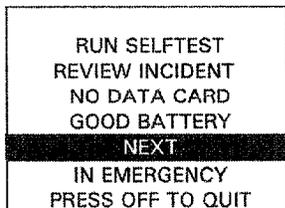
uninterrupted view of the "eye" in the other. (See the diagram on the back of the first page of this manual.) The two devices should be no more than 1 meter apart.

5. Select SEND TIME from the CLOCK screen on the "sending" HeartStart FR2+.

6. Select RECEIVE TIME from the CLOCK screen of the "receiving" FR2+.

```
RECEIVE TIME
EXIT

READY TO RECEIVE

CHECK SENDER
```

7. A new screen comes up. Until the two FR2+ devices are properly positioned, the screen on the receiving FR2+ displays READY TO RECEIVE and prompts you to check the sending FR2+. The screen on the sending FR2+ displays READY TO SEND and prompts you to check the receiving FR2+.

8. Clock settings are automatically transferred as soon as the infrared ports are correctly aligned.

Using Advanced Mode Features

The HeartStart FR2+ provides an advanced mode that allows responders who are appropriately trained to override the programmed FR2+ protocol and take responsibility for certain aspects of the operating sequence used by the FR2+ to treat the patient.

As described earlier in this chapter, the factory default setup of the FR2+ must be modified to provide access to advanced mode features. This requires use of the administration function of the M3864A training & administration pack.

If you are an expert user authorized by your Medical Director to modify setup, hold down both the Option buttons while installing the training & administration pack in the FR2+, then select SETUP. Then select MODIFY SETUP from the SETUP menu. Select ADVANCED from the third menu of the MODIFY SETUP menu.

ADMINISTRATION		SETUP		MODIFY SETUP	
		RETURN		RETURN	
SETUP		RECEIVE SETUP		ADVANCED	OFF
CLOCK		READ SETUP		CPR PROMPT	LONG
		MODIFY SETUP			
		SEND SETUP		PROMPT INTERVALS	
REMOVE BATTERY		WRITE SETUP		MONITOR	1.0
TO QUIT				ADVANCED USE	0.5
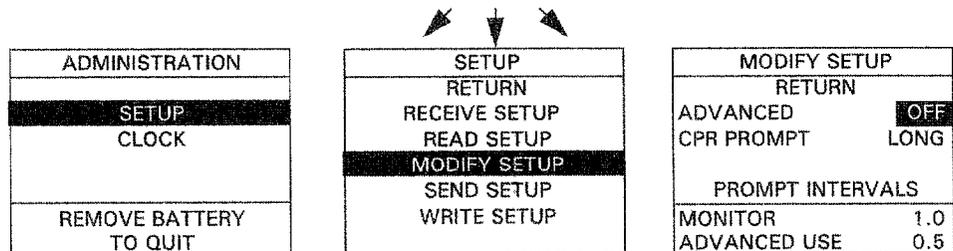
Using the upper Option button, scroll through the available settings for ADVANCED. The advanced mode options available are based on the FR2+

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model used. For the M3860A, the user can select ANALYZE, CHARGE, or OFF. For the M3861A the user can select only ANALYZE or OFF. (Detailed directions for use are supplied with the training & administration pack.)

CAUTION: Alteration of the factory default setup of the FR2+ can affect its performance and should be performed under the authorization of your Medical Director. Modifications to device operation resulting from changes to the default settings should be specifically covered in user training.

CAUTION: The HeartStart FR2+ advanced mode's MANUAL CHARGE feature is intended for use only by authorized operators who have been specifically trained in cardiac rhythm recognition and in defibrillation therapy using manual charge and shock delivery.

The ANALYZE feature is particularly useful for organizations that include responders who have Basic Life Support (BLS) training as well as more highly trained responders who may be certified in Advanced Life Support (ALS). In such situations, the Medical Director may set up a "tiered-response" system. The HeartStart FR2+ is specifically designed to provide different product features appropriate to each tier of responder.

In a scenario where a BLS responder is the first on the scene of an incident, he or she is trained to treat the patient immediately – for example, to check for breathing and responsiveness; to apply the defibrillator pads and connect them to the HeartStart FR2+; and to follow the voice and text prompts provided by the HeartStart FR2+ in its automated (AED) mode. When an ALS-trained responder arrives, the BLS responder "hands off" the patient's care to the more highly trained responder.

Because these second-tier responders have advanced training and developed clinical skills, they may be authorized to access the advanced mode features of the HeartStart FR2+. These include user-initiated analysis and manual charge and disarm control.

Using the manual analyze feature

The Manual Analyze feature is available in both the M3860A and the M3861A models, when enabled in setup.

To enter the advanced mode during use of an FR2+ that has this feature enabled, press both Option buttons simultaneously. This brings up a screen that includes a highlighted line at the bottom, labeled ANALYZE, with an arrowhead pointing to the lower Option button.

0:43   2 ♪

ANALYZE>

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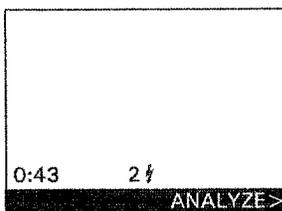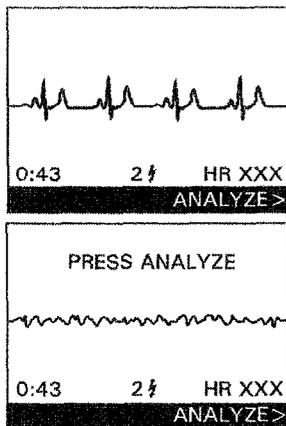
In the M3861A HeartStart FR2+, the patient's ECG is not displayed; in the M3860A, the display includes the patient's ECG and heart rate.

Press the lower Option button (ANALYZE) to initiate rhythm analysis by the FR2+. If a shock is advised, the FR2+ automatically charges, and prompts you to press the Shock button.

After shock delivery, the HeartStart FR2+ returns to the advanced mode display and monitors the patient's heart rhythm. If a potentially shockable rhythm is detected, the text and voice prompts advise you to PRESS ANALYZE.

NOTE: If you do *not* press the lower Option button (labeled ANALYZE) to initiate rhythm analysis when prompted, the HeartStart FR2+ does *not* analyze and prompt if a shock is advised. It is important that you understand that entering the advanced mode entails taking responsibility for these functions.

If the rhythm analysis results in a Shock Advised decision, the FR2+ begins charging, prompts you to press the Shock button, and displays a MANUAL DISARM option at the top of the screen. If for any reason you want to cancel the shock, press the upper Option button to disarm the FR2+.

To return to non-manual, AED mode operation, turn the FR2+ off by pressing the On/Off button. Then turn the FR2+ on by pressing the On/Off button again.

Using the manual charge feature (M3860A only)

The manual charge feature is available only in the M3860A, when enabled in setup.

To enter the advanced mode during use of an FR2+ that has this feature enabled, press both Option buttons simultaneously. This brings up a screen that includes a highlighted line at the top, labeled MANUAL, with an arrowhead pointing to the upper Option button, and another at the bottom, labeled ANALYZE, with an arrowhead pointing to the lower Option button.
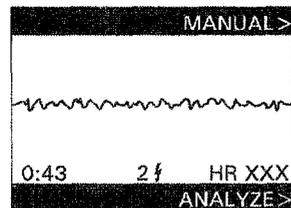
When the advanced mode is entered, display of the patient's ECG and heart rate is automatically initiated.

Pressing the lower Option button (ANALYZE) provides user-initiated rhythm analysis as described above. Pressing the upper Option button (MANUAL) brings up a new screen.

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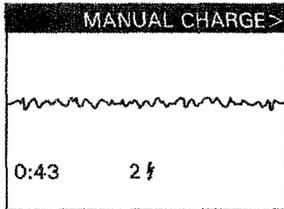
The highlighted top line is labeled MANUAL CHARGE, with an arrowhead pointing to the upper Option button.

```
MANUAL CHARGE >


ᴡᴡᴡᴡᴡᴡᴡᴡᴡᴡ

0:43      2 ⚡
```

If the ECG display shows that, in your expert clinical judgment, the patient has a shockable rhythm, press the upper Option button (MANUAL CHARGE). The HeartStart FR2+ will immediately charge for shock delivery.

As soon as charging begins, the screen message changes to CHARGING, STAND CLEAR, and the label for the arrowhead pointing to the upper Option button changes to MANUAL DISARM.

```
MANUAL DISARM >
CHARGING
STAND CLEAR
ᴡᴡᴡᴡᴡᴡᴡᴡᴡᴡ

0:43      2 ⚡
```
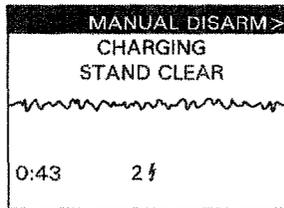
The FR2+ beeps while it is charging. When the beeping changes to a continuous tone and the Shock button light flashes, press the Shock button to deliver a shock. However, if the ECG display shows that the patient's rhythm has changed to a non-shockable rhythm, press the upper Option button to disarm the HeartStart FR2+.

After shock delivery, the HeartStart FR2+ returns to the initial advanced mode screen. To return to non-manual, AED mode operation, turn the FR2+ off by pressing the On/Off button. Then turn the FR2+ on by pressing the On/Off button again.

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M3860A/M3861A HEARTSTART FR2+

7 Data Management and Review

Overview

The HeartStart FR2+ is designed to make it easy to manage incident data. Some information is automatically stored in the internal memory of the HeartStart FR2+. More detailed data can be stored on a data card if desired. The incident information stored in the HeartStart FR2+'s internal memory, or a summary of the information recorded on the data card, can then be displayed on the HeartStart FR2+ screen for review. In addition, HeartStart Event Review* software can be used on a personal computer to store and review the detailed recorded information from a data card.

Recording Incident Data

The HeartStart FR2+ has two ways of recording information about an emergency incident so that it can be reviewed after the incident: in internal memory and on an optional data card.

Recording data in internal memory

Summary data for an incident is automatically recorded in internal memory by the FR2+ while you are using it.

Recording data on a data card

The M3854A data card can be used to store several hours of detailed incident data, including events and ECG.

IMPORTANT NOTE: To record incident data on a data card, the data card must be installed *before* you turn on the FR2+.

CAUTION: The FR2+ is designed to be used only with Philips-approved accessories. The FR2+ may perform improperly if non-approved accessories are used.

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*   HeartStart Event Review software was previously sold as CodeRunner software.

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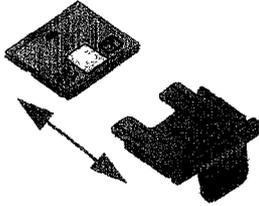
To install a data card:

1. Make sure the data card is clean and dry.

2. Load the data card into its plastic tray, with the tray's "tongue" fitting over the matching yellow area on the data card. The label on the card should face up. The label has an arrow indicating which side to insert into the data card port.

3. Make sure the FR2+ is off (in standby mode), or that the battery has been removed.

4. Hold the loaded tray by its handle and gently insert the tray into the data card port on the right side of the FR2+. Push the tray all the way into the port until only the tab remains outside the FR2+ case. Do not force the tray into the port. If the tray is hard to insert, remove it and make sure that the arrow label is face up and pointing toward the data card port.

The data card will automatically record incident data the next time the HeartStart FR2+ is turned on.

To avoid running out of data card space during an incident, it is recommended that each data card be used to record the information for only one incident and that it be replaced after each use of the FR2+.

If you record information from more than one incident on a data card, it is important to review how much time is left on the used data card before recording a new incident. To do this, load the data card into the data card tray, insert the tray in the FR2+, then remove and reinstall the battery. The first screen displayed shows how much recording time remains on the card.

NOTE: During an incident, if for any reason you turn off the FR2+ *for less than five minutes,* the FR2+ considers this to be a "continued use" situation, and:
- the information stored about the incident is saved,
- additional events recorded after the device is turned back on will be treated as part of the same incident, and
- the selftest will *not* automatically run if the battery is replaced.

IMPORTANT NOTE: Do not remove the battery while incident data are being recorded to a data card. To ensure that no incident data are lost, turn the FR2+ off (return it to standby mode) before replacing the battery.

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To replace a data card:

IMPORTANT: You must turn the FR2+ off (return it to standby mode) *before* you remove the data card, to ensure that no incident data are lost.

1. Press the On/Off button to turn off the FR2+. Never replace the data card unless the FR2+ is turned off.

2. Remove the loaded data card tray by grasping its handle and pulling it out of the port.

3. Remove the data card from the tray.

4. Give the data card to the appropriate person in your organization.

5. Because it helps seal the FR2+ against moisture, *the data card tray should always be reinserted into the port of the FR2+.* Either load a new data card into the tray and insert it, or insert the empty data card tray into the port.

Reviewing Incident Data

Reviewing data from internal memory

Summary information from the last incident that is stored in the internal memory of the HeartStart FR2+ can be displayed on its screen for review. To review this information:

1. Remove the data card if one is installed and unplug the pads connector.

2. Remove and reinstall the battery. (Make sure you are using the gray M3863A FR2 standard battery or the blue M3848A rechargeable battery, not the yellow training & administration pack.)

3. Select REVIEW INCIDENT from the menu. A new screen comes up.

4. Observe and record, if desired, the summary information displayed on the screen:

   • how long the incident recorded by the FR2+ lasted, and

   • how many shocks were delivered during the incident.

This information stays in the FR2+'s memory and can be displayed for review until the next time the FR2+ is used. At that time, the data from the new incident will be displayed.

```
      RUN SELFTEST
     REVIEW INCIDENT
      NO DATA CARD
      GOOD BATTERY
         NEXT
      IN EMERGENCY
    PRESS OFF TO QUIT
```

```
    REVIEW INCIDENT
        RETURN

   SUMMARY INFORMATION
  ELAPSED TIME:     3:18
  SHOCKS DELIVERED:    6
```

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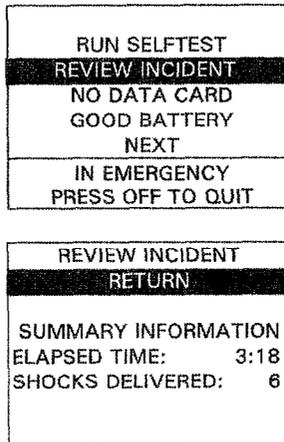
Reviewing data from a data card

If a data card is installed when the HeartStart FR2+ is turned on for use during an incident, the HeartStart FR2+ automatically records detailed information on the data card. To review this information on the HeartStart FR2+ screen:

```
REVIEW INCIDENT
    RETURN
  REVIEW EVENTS
   REVIEW ECG
ELAPSED TIME:      3:18
SHOCKS DELIVERED:     6
FIRST SHOCKS AT:
  00:18   01:10   01:49
```

1. Make sure the training & administration pack is *not* installed.

2. Make sure the data card is installed. Unplug the pads connector.

3. Remove and reinstall the battery.

4. Select REVIEW INCIDENT from the menu. A new screen comes up. This screen displays:

   • ELAPSED TIME – how long the incident recorded by the FR2+ lasted,*

   • SHOCKS DELIVERED – how many shocks were delivered during the incident, and

   • FIRST SHOCKS AT – the times at which the first three shocks were delivered.

   NOTE: If the data card does not contain event data, only the summary information from FR2+ internal memory will be displayed when REVIEW INCIDENT is selected.
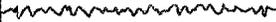
```
REVIEW EVENTS
    RETURN
  NEXT EVENTS
POWER ON         0:00
PADS ON          0:04
SHOCK ADVISED    0:13
ARMED            0:18
SHOCKED          0:22
```

5. To review the events that occurred during the incident, select REVIEW EVENTS. A new screen comes up. This and following screens, accessed by selecting NEXT EVENTS, display elapsed time information for critical activities in using the FR2+. These include:

   • **POWER ON** – when the FR2+ was turned on,

   • **PADS ON** – when the defibrillator pads were connected,

   • **SHOCK ADVISED** – when a shock was advised,

   • **ARMED** – when the FR2+ charged for shock delivery,

   • **SHOCKED** – when a shock was delivered,

   • **SHOCK ABORTED** – when a shock was aborted,

   • **PAUSE FOR CPR** – when a pause occurred

   • **POWER OFF** – when the FR2+ was turned off

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*   The FR2+ displays elapsed time to a maximum of 99:59 minutes. If the elapsed time of use extends beyond this figure, the minutes are represented by "??" but the seconds are displayed. However, total elapsed time will be recorded on an installed data card for later review with HeartStart Event Review data management software.

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Additional information may be displayed if your FR2+ is using a revised setup allowing advanced mode operation.

REVIEW EVENTS	
RETURN	
NEXT EVENTS	
NO SHOCK ADVSD	0:31
PAUSE FOR CPR	0:40
RESUME ANALYZE	1:00
MAN OVERRIDE	1:10
MANUAL ANALYZE	1:15

REVIEW EVENTS	
RETURN	
NEXT EVENTS	
MANUAL CHARGE	1:30
DISARMED	1:35
SHOCK ABORTED	1:40
ADVANCED USE	2:00
PADS OFF	2:20

REVIEW EVENTS	
RETURN	
POWER OFF	2:25

REVIEW INCIDENT	
RETURN	
REVIEW EVENTS	
REVIEW ECG	
ELAPSED TIME:	3:18
SHOCKS DELIVERED:	6
FIRST SHOCKS AT:	
00:18 01:10 01:49	

REVIEW ECG
RETURN
NEXT ECG SEGMENT

6. To review the first six seconds of the recorded presenting ECG for the incident, select REVIEW ECG. A new screen comes up. This screen displays a three-second segment of the presenting ECG from the incident.

7. Select NEXT ECG SEGMENT to review the second three-second segment of the presenting ECG.

Data cards can be reused if desired. Using a personal computer running HeartStart Event Review software, you can copy the information from a data card, then erase the card and reuse it in the FR2+.

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Notes

A   Accessories for the HeartStart FR2+

HeartStart Accessories

Accessories for the HeartStart FR2+ available separately from Philips
Medical Systems include the following:

- Spare M3863A FR2 standard battery (recommended)
- DP2/DP6 adult defibrillator pads
- M3870A FR2 infant/child reduced-energy defibrillator pads
- Spare M3853A data card tray
- M3854A data card and tray
- M3868A fabric carrying case
- M3869A vinyl carrying case
- M3857A wall mount bracket
- M3848A FR2+ rechargeable battery[*][†]
- M3849A charger, for the M3848A FR2+ rechargeable battery only;
  includes power cord
- 68-PCHAT fast response kit (pouch containing a pocket mask, a
  disposable razor, 2 pairs of gloves, a pair of paramedics scissors, and an
  absorbent wipe)
- M3873A/M3874A FR2+ ECG assessment module, for use only with an
  M3860A FR2+ configured for ECG display, for connection to ECG
  electrodes per AAMI (M3873A) or IEC (M3874A) convention[†]
- M3864A training & administration pack
- M3855A charger, for the training & administration pack only; includes
  power cord
- PFE7023D/PFE7024D defibrillator cabinets
- 07-10900 training pads[‡]
- YC hardshell waterproof carrying case

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[*]   The M3848A FR2+ rechargeable battery is designed for environments in which the FR2+
      Defibrillator is expected to see frequent use. This battery is not designed for use in aircraft.
      It is recommended that this battery not be used as a spare or backup battery and, due to its
      shorter standby life, that it not be used as the primary or spare battery in applications
      where the FR2+ Defibrillator is infrequently used, such as the home, commercial business,
      or commercial airlines environments.
[†]   These products can be used only with FR2+ Defibrillators running software version 1.5 or
      higher.
[‡]   IMPORTANT: Never store training pads with the defibrillator.

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Suggested Additional Items

It may be useful to keep some additional items with your HeartStart FR2+ for use if needed when an incident occurs. Some suggested supplies include:

- a pair of paramedic's shears or scissors[*]
- a disposable razor designed for removing chest hair[*]
- a pocket mask or face shield[*]
- disposable gloves[*]
- a towel or antiseptic wipes[*]
- a source of oxygen

Your medical director may have other requirements for supplies.

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[*]   Contained in the fast response kit available from Philips Medical Systems

M3860A/M3861A HEARTSTART FR2+

B

B   Technical Specifications

The specifications for the HeartStart FR2+ provided in this chapter apply to both the M3860A and M3861A, unless otherwise noted. Additional information can be found in the *Technical Reference Manual* for the FR2 Defibrillator, located online at www.medical.philips.com.

HeartStart FR2+ Defibrillator Specifications

Physical

category	nominal specifications
Size	2.6" high x 8.6" wide x 8.6" deep (6.6 cm x 21.8 cm x 21.8 cm).
Weight	Approximately 4.7 lbs (2.1 kg) with M3863A FR2 standard battery installed. Approximately 4.5 lbs (2 kg) with optional M3848A FR2+ rechargeable battery installed.

Environmental

category	nominal specifications
Operating Temperature and Humidity	32° to 122° F (0° to 50° C). 0% to 95% relative humidity (non-condensing).
Standby Temperature and Humidity	32° to 109° F (0° to 43° C). 0% to 75% relative humidity (non-condensing). Applies to HeartStart FR2+ with battery installed and stored with defibrillator pads.
Altitude	Meets MIL-810E 500.3, Procedure II (-500 feet to 15,000 feet).
Shock/Drop Abuse Tolerance	Meets MIL-STD-810E 516.4, Procedure IV (after a 1 meter drop to any edge, corner, or surface, in standby mode).
Vibration	Meets MIL-STD-810E 514.4-17.
Sealing	With data card tray and battery installed, meets IEC 529 class IP54.
ESD	Meets EN 61000-4-2:1998 Severity Level 4.
EMI (Radiated)	Meets EN 60601-1-2 limits (1999), method EN 55011:1998 Group 1 Level B.

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category	nominal specifications
EMI (Immunity)	Meets EN 60601-1-2 limits (1993), method EN 61000-4-3:1998 Level 2 (3 V/m and 10 V/m at 26 MHz to 1 GHz).
Avionic Module	Meets RTCA/DO 160D 1997 Section 21 (Category M - Charging).

Defibrillator

category	nominal specifications
Waveform Parameters	Biphasic truncated exponential. Waveform parameters are automatically adjusted as a function of patient defibrillation impedance. In the diagram at left, A is the duration of phase 1 and B is the duration of phase 2 of the waveform, C is the interphase delay, V_p is the peak voltage, and V_f the final voltage. The HeartStart FR2+ delivers shocks to load impedances from 25 to 180 ohms. The duration of each phase of the waveform is dynamically adjusted based on delivered charge, in order to compensate for patient impedance variations, as shown below:

adult defibrillation

load resistance (ohms)	phase 1 duration (ms)	phase 2 duration (ms)	delivered energy (J)
25	2.8	2.8	140
50	4.09	4.09	150
100	9.0	6.0	157
125	12.0	8.0	161
150	12.0	8.0	157

pediatric defibrillation
(using M3870A FR2 infant/child reduced-energy defibrillator pads)

load resistance (ohms)	phase 1 duration (ms)	phase 2 duration (ms)	delivered energy (J)
25	4.1	4.1	35
50	5.8	3.8	48
100	7.2	4.8	55
125	7.2	4.8	54
150	9.0	6.0	55
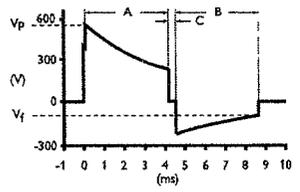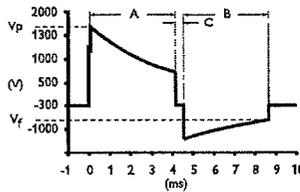
NOTE: The values given are nominal. Because of the effect of the M3870A FR2 infant/child pads' attenuation circuitry on the defibrillator's impedance compensation feature, the actual phase durations for a given load resistance on the table above could be those of an adjacent row.

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category	nominal specifications
Energy	Using adult defibrillator pads: 150 J nominal into a 50 ohm load. Using infant/child reduced energy defibrillator pads: 50 J nominal into a 50 ohm load. Sample pediatric energy doses:

age	energy dose
newborn	14 J/kg
1 year	5 J/kg
2 – 3 years	4 J/kg
4 – 5 years	3 J/kg
6 – 8 years	2 J/kg

Doses indicated are based on CDC growth charts for the 50th percentile weights for boys:

> National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion. *CDC growth charts: weight for age percentiles*, revised and corrected November 28, 2000. Atlanta, GA: Centers for Disease Control and Prevention © 2000

category	nominal specifications
Charge Control	Controlled by Patient Analysis System for automated operation. Can be programmed for manual initiation using advanced mode of the M3860A.
Charge Time (from "Shock Advised")	≤ 10 seconds typical, including confirming analysis. Charge time increases near end of battery service life.
Shock-to-Shock Cycle Time	< 20 seconds typical, including analysis, in AED mode.
Charge Complete Indicator	Shock button flashes, audio tone sounds.
Disarm (AED mode)	Once charged, the HeartStart FR2+ will disarm if: • patient's heart rhythm changes to non-shockable rhythm, *OR* • a shock is not delivered within 30 seconds after the FR2+ is armed, *OR* • the PAUSE button (if enabled) is pressed, *OR* • the On/Off button is pressed to turn off the FR2+, *OR* • the defibrillator pads are removed from the patient or the pads connector is disconnected from the FR2+.

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category	nominal specifications
Disarm (advanced modes)	Once charged, the HeartStart FR2+ will disarm if: **In advanced mode ANALYZE** • the manual disarm button is pressed, OR • a patient's heart rhythm changes to non-shockable rhythm, OR • a shock is not delivered within 30 seconds after the FR2+ is armed, OR • the On/Off button is pressed to turn off the FR2+, OR • the defibrillator pads are removed from the patient, OR • the pads connector is disconnected from the FR2+ **In advanced mode CHARGE (M3860A only)** • the manual disarm button is pressed, OR • a shock is not delivered within 90 s after charging, OR • the On/Off button is pressed to turn off the FR2+, OR • the defibrillator pads are removed from the patient, OR • the pads connector is disconnected from the FR2+.
Shock Delivery Vector	Via adult defibrillator pads placed in the anterior-anterior (Lead II) position or via FR2 infant/child reduced-energy defibrillator pads placed in the anterior-posterior position.

ECG Analysis System

category	nominal specifications
Function	Evaluates impedance of defibrillator pads for proper contact with patient skin, and evaluates the ECG rhythm and signal quality to determine if a shock is appropriate.
Protocols	Follows pre-programmed settings to match local EMS guidelines or medical protocols. The settings can be modified using the setup options.
Shockable Rhythms	Ventricular fibrillation (VF) and certain ventricular tachycardias, including ventricular flutter and polymorphic ventricular tachycardia (VT). The HeartStart FR2+ uses multiple parameters to determine if a rhythm is shockable. *NOTE: For safety reasons, some very low-amplitude or low-frequency rhythms may not be interpreted as shockable VF rhythms. Also, some VT rhythms may not be interpreted as shockable rhythms. CPR rates significantly above 100 compressions per minute can cause incorrect or delayed analysis by the HeartStart FR2+.*
Asystole	On detection of asystole, provides CPR prompt at programmed interval.

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M3860A/M3861A HEARTSTART FR2+

category	nominal specifications
Pacemaker Detection	On detection of a pacemaker (in advanced mode or with M3873A/M3874A FR2+ ECG assessment module), provides screen display of PACEMAKER DETECTED alert. M3860A includes pacemaker artifact in ECG display. In both models, pacemaker artifact is removed from the signal for rhythm analysis.

Display

category	nominal specifications
Monitored ECG Lead	ECG information is received from adult defibrillator pads in anterior-anterior (Lead II) position or from FR2 infant/child reduced-energy defibrillator pads in anterior-posterior position. (Displayed on M3860A only.) ECG information can also be displayed in the M3860A using the FR2+ ECG assessment module. *NOTE: The ECG display provided by the FR2+ Defibrillator is not is not intended to provide diagnostic or ST segment interpretation.*
Display Range (M3860A only)	Differential: ±2 mV full-scale, nominal.
Screen Type	High-resolution liquid crystal display (LCD) with backlight.
Screen Dimensions	2.8" wide x 2.3" high (70 mm x 58 mm).
Sweep Speed (M3860A only)	23 mm/s nominal.
ECG Display	3 second segments displayed (M3860A only).
Frequency Response (Bandwidth)	Nondiagnostic rhythm monitor 1 Hz to 20 Hz (-3 dB), nominal.
Sensitivity	1.16 cm/mV, nominal.
Heart Rate Displayed (Normal Sinus Rhythm)	30 to 300 bpm, updated each analysis period. Displayed (M3860A only) during monitoring and advanced modes.

Controls and indicators

category	nominal specifications
LCD Screen	High-resolution, backlighted LCD screen, displays text messages and (model M3860A only) ECG.

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category	nominal specifications
Controls	On/Off button Shock button Option buttons
LED indicators	Connector socket LED, flashes to indicate socket location. LED is covered when defibrillator pad connector is properly inserted. Shock button LED flashes when defibrillator is armed.
Audio Speaker	Provides voice prompts (volume is adjustable via Setup screen).
Beeper	Chirps when a selftest has failed. Provides various warning beeps during normal use.
Status Indicator	Status indicator LCD displays device readiness for use.
Low Battery Detection	Automatic during daily periodic selftesting.
Low Battery Indication	Solid or flashing red X Status Indicator on front panel; screen display LOW BATTERY or REPLACE BATTERY warning, as appropriate.

Accessories Specifications

M3863A FR2 standard battery

category	nominal specifications
Battery Type	12 VDC, 4.2 Ah, lithium manganese dioxide. Disposable, long-life primary cell.
Capacity	When new, a minimum of 300 shocks or 12 hours of operating time at 77° F (25° C).
Shelf Life (prior to installation)	Typically, 5 years from date of manufacture when stored under standby environmental conditions in original packaging.
Standby Life (after installation)	Typically, 5 years. >4 years when stored under standby environmental conditions (battery installed, FR2+ unused).
Status Indicators	Good battery: flashing black hourglass on the front panel of the FR2+. Low battery: flashing red X on the front panel of the FR2+. Dead battery: solid red X on the front panel of the FR2+.
Storage Temperature	32° to 109° F (0° to 43° C).

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M3860A/M3861A HEARTSTART FR2+

(Optional) M3848A FR2+ rechargeable battery

category	nominal specifications
Battery Type	11.3 VDC, 6.5 Ah, lithium ion. Rechargeable cell using the M3849A charger.
Capacity	When freshly charged and used at 77° F (25° C), provides a minimum of 80 (typically 100) shocks, or 3.5 hours (typically 5 hours) of ECG display time only, before recharging is indicated.
Status Indicators	Good battery: bar graph on display screen indicating remaining power level. Low battery: flashing red X on the front panel of the FR2+ (When low battery indicator appears, there is still enough energy to deliver 9 shocks plus 15 minutes of ECG display time). Dead battery: solid red X on the front panel of the FR2+.
Storage Temperature	32° to 109° F (0° to 43° C).
Standby Life (after Installation)	6 months when installed fully charged in a defibrillator labeled FR2+.

(Optional) M3849A charger

category	nominal specifications
Application	For use with M3848A FR2+ rechargeable battery only.
Power Requirements	100 to 240 VAC, 47 to 63 Hz, 30 Watts.
Environmental Requirements	32° to 122° F (0° to 50° C). 0% to 95% relative humidity (non-condensing).
Conformance Testing	International: EN60335-1:1994 Class 1 North America: UL 1310 Class 2

M3870A and DP2/DP6 defibrillator pads

category	nominal specifications
Pads, Cable, and Connector	Disposable and self-adhesive. DP2/DP6 adult defibrillator pads have a nominal active surface area of 100 cm^2 each and are provided in a sealed package with an integrated 122 cm (48 inch), typical, cable and connector. M3870A FR2 infant/child reduced-energy defibrillator pads have a nominal active surface area of 44 cm^2 each and are provided in a sealed package with an integrated 122 cm (48 inch), typical, cable and connector incorporating attenuating electronics.

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category	nominal specifications
Defibrillator Pad Requirements	Use only DP2/DP6, M3870A, M3713A, and M3716A defibrillator pads with the HeartStart FR2+. Place the pads on the patient as illustrated on each pad.

(Optional) M3854A data card

category	nominal specifications
Capacity	8 hours of event and ECG data, or 60 minutes with voice recording.

(Optional) M3864A training & administration pack

category	nominal specifications
Battery Type	12 V, 1.1 Ah, nickel metal hydride. Disposable, rechargeable cell using the M3855A charger.
Capacity	Provides 4 hours of operating time at 77 °F (25 °C).
Status Indicators	Low battery: flashing red X on the front panel of the FR2+. Dead battery: solid red X on the front panel of the FR2+.
Storage Temperature	50° to 104° F (10° to 40° C).

(Optional) M3855A charger

category	nominal specifications
Application	For use with M3864A training & administration pack only.
Power Requirement	With appropriate power cord, any AC mains power input or inverter-type power sources.
Environmental Requirements	32° to 113° F (0° to 45° C). 35% to 85% relative humidity (non-condensing).
Conformance Testing	International: EN60335-1:1994 Class I North America: UL 1310 Class 2

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M3860A/M3861A HEARTSTART FR2+

(Optional) M3873A/M3874A FR2+ ECG assessment module

category	nominal specifications
Application	For use with the FR2+ M3860A with ECG display enabled and running version 1.5 software or higher (denoted by *FR2+* on the front panel or rear label).
Length and weight	100 inches (182 cm); ≤ 1 lb. (2.2 kg)
Operating Temperature and Humidity	32° to 122° F (0° to 50° C); 0% to 95% relative humidity (non-condensing).
Storage Temperature and Humidity	32° to 109° F (0° to 43° C); 0% to 75% relative humidity (non-condensing).
Patient Lead Wire Designation	M3873A (AAMI): positive lead – red, negative lead – white, reference lead – black. M3874A (IEC): positive lead – green, negative lead – red, reference lead – yellow
Typical Lead II connection	Lead II vectors: positive – left leg, negative – right arm, reference – left arm. Other limb vectors can be obtained by different electrode positions.
Battery Type	3 V, 1 Ah, poly-carbonmonofluoride lithium (LiCFx). Non-replaceable disposable primary cell.
Service Life	Typically, 5 years.
Performance with FR2+ Defibrillator	Meets environmental specifications cited for FR2+ Defibrillator on page B1 through B2.

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Notes

M3860A/M3861A HEARTSTART FR2+

C Glossary of Symbols and Controls

Instructions for Use

symbol	description
$C\epsilon_{0123}$	Meets the requirements of the European medical device directives.
♻	Printed on recycled paper.

HeartStart FR2+ M3860A and M3861A Defibrillator Symbols and Controls

Control panel and back label

symbol	description
ON•OFF	On/Off button. Turns the HeartStart FR2+ on or off; disarms HeartStart FR2+, stops automatic self-test. When the optional training & administration pack is being used in the Training function, this button is used to select and exit training scripts.
⚡	Shock button. Delivers shock to patient when the HeartStart FR2+ is charged.
●●	Upper and lower Option buttons. Allow you to move around in and select an item from a display menu, provide adjustment of display screen contrast.
👤	Defibrillation protection. Defibrillation protected, type BF patient connection.

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symbol	description
	High voltage.
	Refer to operating instructions.
CE 0123	Meets the requirements of the European medical device directives.
CSA c us	This product has passed relevant safety tests by CSA, a nationally recognized test lab.
IP54	With data card tray and battery installed, meets IEC 529 class IP54.

HeartStart FR2+ display screen

symbol	description
HR XXX	Heart rate.
	Number of shocks delivered.
XX:XX	Time. How much time (minutes:seconds) has passed since the HeartStart FR2+ was turned on.
TEMPERATURE	Temperature. Recommended storage temperature range has been exceeded since the last battery insertion self-test.
SETUP	Setup. Setup has been lost from memory; factory default setup is being used. Contact Medical Director for revised setup.
REV. XXXX.XX XXXX	Software. The version of software used in your HeartStart FR2+.

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Status indicator

symbol	description
	Flashing black hourglass. Ready for use.
	Solid red X. Not ready for use. (See Chapter 4, "Maintaining, Testing, and Troubleshooting Your HeartStart FR2+.")
	Flashing red X. Troubleshooting required. (See Chapter 4, "Maintaining, Testing, and Troubleshooting Your HeartStart FR2+.")

Accessories Symbols

M3870A and DP2/DP6 defibrillator pads

symbol	description
	These pads are disposable and are for single patient use only.
	Pouch contents: one pair of defibrillator pads.
43° C 110° F 0° C 32° F	Store the pads at temperatures between 0° and 43° C (32° and 110° F).
!	Refer to operating instructions.
NON-STERILE	Non-sterile.
LATEX	This product does not contain natural rubber latex.
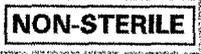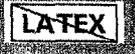
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Glossary of Symbols and Controls

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symbol	description
LOT	Lot number.
USE BEFORE	Use the pads before the date shown. Date format is YYYY-MM.
Rx only	CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Pad placement for adults. (DP2/DP6)
	For use with Philips Heartstream/HeartStart and Laerdal HeartStart ForeRunner, FR, and FR2 AEDs. (DP2/DP6)
LAERDAL HEARTSTART 911 · 1000 2000 · 3000	Not for use with Laerdal HeartStart models 911, 1000, 2000, 3000. (DP2/DP6)
	Pad placement for infants and children younger than 8 years or lighter than 55 pounds (25 Kg). (M3870A)
CE	Meets the requirements of the EMC directives. (DP2/DP6)
CE 0123	Meets the requirements of the European medical device directives. (M3870A)
=1	Box contents = 1 pouch. (M3870A)
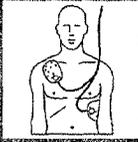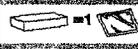
M3860A/M3861A HEARTSTART FR2+
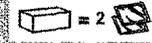
symbol	description
☐ = 2 ▨	Box contents = 2 pouches. (DP2)
☐ = 6 ▨▨▨	Box contents = 6 pouches. (DP6)
↑	This side up.
♓	Fragile.
☂	Protect from moisture.
♻	Printed on recycled paper.

M3863A standard battery and M3848A FR2+ rechargeable battery

symbol	description
⊘	Do not crush.
⊘	Do not expose to high heat or open flames. Do not incinerate.
⊘	Do not mutilate or open.
⧗ Install Before	Install before the date shown on this label. Date format is MM-YYYY.

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Glossary of Symbols and Controls

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symbol	description
⚠	Refer to operating instructions.
LiMnO₂	Lithium manganese dioxide battery chemistry (M3863A)
LiION	Lithium ion battery chemistry (M3848A)
DC 12V ⎓	12 volts direct current output.
⬇	Insert into FR2+ in this direction.
CE 0123	Meets the requirements of the European medical device directives.
🍷	Fragile.
☂	Protect from moisture.
+ QTY (1)	Contains one battery.
♻	Printed on recycled paper.
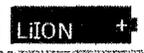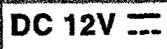
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M3860A/M3861A HEARTSTART FR2+

M3849A charger
for the M3848A FR2+ rechargeable battery

symbol	description
⚠	Refer to operating instructions.
⚡	High voltage.
☂	Protect from moisture.
◇	On/Off indicator.
🔋	Charger status indicator.
CE	Meets the requirements of the EMC directives.
CSA us	This product has passed relevant safety tests by CSA, a nationally recognized test lab.
C N11695 V00341	This product has been certified by the Australian Communication Authority.
♲	Printed on recycled paper.
⊝	Electrical input.
⊙	Electrical output

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M3873A/M3874A FR2+ ECG assessment module
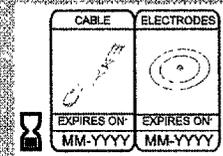
symbol	description
CABLE ELECTRODES / EXPIRES ON MM-YYYY / EXPIRES ON MM-YYYY	Use the cable and electrodes before the respective dates shown on this label.
<44 HR 60C(140F) / <95% 43C(110F) / 0C(32F) / -20C(-4F)	Ship and store the product within the temperature ranges shown.
(body with electrodes)	Place the electrodes as shown.
CE	Meets the requirements of the EMC directives.
LOT	Lot number.
!	Refer to operating instructions.
(recycle symbol)	Printed on recycled paper.
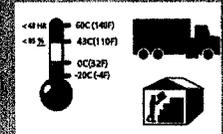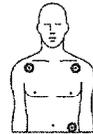
M3864A training & administration pack

symbol	description
!	Refer to operating instructions.

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symbol	description
	Do not crush.
	Do not expose to high heat or open flames. Do not incinerate.
	Do not mutilate or open.
	Nickel metal hydride battery chemistry.
DC 12V	12 volts direct current output.
	Insert into FR2+ in this direction.
CE	Meets the requirements of the EMC directives.
	Kit contains Training & Administration Pack, Instructions for Use, and set of training pads.
	Ship and store the product within the temperature ranges shown.
	This side up.
	Fragile.
	Protect from moisture.

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Glossary of Symbols and Controls

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symbol	description
♻	Printed on recycled paper.

M3855A charger
for the M3864A training & administration pack)

symbol	description
⚠	Refer to operating instructions.
⚡	High voltage.
☂	Protect from moisture.
◇	On/Off indicator.
🔋	Charger status indicator.
CE	Meets the requirements of the EMC directives.
⟲	Electrical input.
⟳	Electrical output.
♻	Printed on recycled paper.

M3860A/M3861A HEARTSTART FR2+

D Glossary of Terms

The terms listed in this Glossary are defined in the context of the HeartStart FR2+ and its use.

advanced mode .... A programmable treatment mode that permits an authorized user to control when the FR2+ starts rhythm analysis and (model M3860A only) when to begin defibrillator charging for shock delivery.

AED .... Automated external defibrillator.

AED mode .... The standard FR2+ treatment mode, with voice and screen prompts guiding the responder through connecting the defibrillator pads, waiting for rhythm analysis, and delivering a shock if needed. In this mode, heart rhythm analysis and monitoring, and shock decision and charging for shock delivery are automatically performed by the FR2+.

ALS .... Advanced Life Support.

analysis .... See "SMART analysis."

arrhythmia .... An unhealthy, often irregular, beating of the heart.

battery .... See "standard battery" and "rechargeable battery."

BLS .... Basic Life Support.

continued use .... A condition in which use of the HeartStart FR2+ is interrupted for less than five minutes (e.g., for battery replacement). When the battery is reinserted or the unit is turned on again, the information stored about the interrupted incident is saved, any additional events recorded after the battery is reinstalled are treated as part of the same incident, and the selftest does *not* automatically run when the battery is reinstalled.

CPR timer .... A programmable period provided by the HeartStart FR2+ during which the responder can administer CPR.

defibrillation .... Termination of cardiac fibrillation by applying electrical energy

defibrillation charge .... Electrical energy stored in the capacitor of the HeartStart FR2+ as it arms for shock delivery.

defibrillation shock .... See "SMART biphasic waveform."

defibrillator pads .... The self-adhesive electrode pads applied to the adult patient's bare chest or pediatric (under 8 years of age or less than 55 lb./25 kg) patient's bare chest and back, and used to detect the patient's heart rhythm and transfer the

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defibrillation shock. Use only DP2/DP6, M3870A, M3713A, and M3716A defibrillator pads with the HeartStart FR2+.

ECG .... Electrocardiogram, a display or printout of the electrical rhythm of the heart as detected through defibrillator pads.

event .... An action recognized or performed by the HeartStart FR2+ as a step in the sequence of using the device in an incident. Examples include: applying the pads and connecting them to the HeartStart FR2+, analyzing heart rhythm, delivering a shock, etc.

fibrillation .... A disturbance of the normal heart rhythm that results in chaotic, disorganized activity that cannot effectively pump blood. Ventricular fibrillation (fibrillation in the lower chambers of the heart) is associated with sudden cardiac arrest.

heart rhythm
(ECG) analysis .... A system used by the FR2+ to determine if the patient's heart rhythm is shockable – ventricular fibrillation (VF) or certain ventricular tachycardias (VTs). See "SMART analysis."

HeartStart Event Review ...... A dedicated data management software system (formerly sold as CodeRunner) for use with the HeartStart FR2+. It is available from Philips Medical Systems on CD or on the world wide web at http://www.medical.philips.com/goto/eventreview.

impedance .... Electrically, this is the total opposition offered by the body to the flow of the electrical shock waveform delivered by the HeartStart FR2+. The FR2+ automatically monitors the electrical impedance between the defibrillator pads placed on the patient's bare skin, and adjusts the shock waveform appropriately.

incident .... The series of events involved in treating a patient with the HeartStart FR2+.

infrared
communications .... A method of sending information using a special part of the light spectrum. It is used to transmit information to and from the HeartStart FR2+ and another FR2+ or a computer running HeartStart Event Review software.

manual charge .... A feature of the advanced mode used by an authorized ALS-certified responder that allows the user to arm the HeartStart FR2+ for shock delivery.

manual disarm .... A feature of the advanced mode used by an authorized ALS-certified responder that allows the user to dump the HeartStart FR2+ charge internally.

monitoring .... A mode of background analysis to determine if patient rhythm has changed to a shockable rhythm.

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M3860A/M3861A HEARTSTART FR2+

non-shockable rhythm	A heart rhythm that the HeartStart FR2+ determines is not appropriate for shock delivery.
NSA	No Shock Advised decision, made by the HeartStart FR2+ based on analysis of the patient's heart rhythm.
pacemaker	External or implanted cardiac pulse generator that stimulates the heart electronically.
pads	See "defibrillator pads."
pause	A defined period during which the HeartStart FR2+ does not perform rhythm analysis.
pediatric defibrillation	Defibrillation of a child under eight years of age or 55 lbs. (25 Kg). It is recommended that FR2 infant/child reduced-energy defibrillator pads be used for pediatric patients.
periodic selftests	Daily, weekly, and monthly tests automatically conducted by the FR2+ when it is in the standby mode. The tests monitor many key functions and parameters of the FR2+, including battery capacity and the state of its internal circuitry.
presenting ECG	The heart rhythm seen by the HeartStart FR2+ when it is first connected to the patient (via the defibrillator pads) and begins rhythm analysis.
prompts	The voice commands and screen text used to guide the responder through use of the HeartStart FR2+ to treat the patient.
protocol	A sequence of operations performed by the HeartStart FR2+ to direct patient care in the AED mode.
protocol timeout	A programmable interval between shocks, used by the HeartStart FR2+ to decide if the shocks are part of the same shock series.
read (data)	A feature of the HeartStart FR2+ that allows it to read setup data from a M3854A data card.
receive (data)	A feature of the HeartStart FR2+ that allows use of its infrared (IR) communications port to receive revised setup and clock settings directly from another device.
rechargeable battery	The M3848A FR2+ rechargeable battery, used with the M3849A charger only.
record voice	An optional feature of the HeartStart FR2+ that allows sound recording to a data card during use of the device in an incident. Activation of this feature requires revision of the HeartStart FR2+'s default settings.

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Glossary of Terms

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rhythm analysis	See "SMART analysis."
send (data)	A feature of the HeartStart FR2+ that allows use of its infrared (IR) communications port to send data directly to another FR2+ or a computer running HeartStart Event Review Web software.
sensitivity	A measure of the ability of the HeartStart FR2+ to reliably detect and identify shockable heart rhythms.
setup	The settings of all programmable operating parameters of the HeartStart FR2+. The factory default setup can be modified using the M3864A training & administration pack.
shock series	One or more shocks, each separated by no more than a preset time (programmed Protocol Timeout). After completion of a shock series, the HeartStart FR2+ automatically pauses for CPR.
shockable rhythm	Ventricular fibrillation and certain ventricular tachycardias associated with sudden cardiac arrest.
shock waveform	See "SMART biphasic waveform."
SMART analysis	The proprietary algorithm used by the FR2+ to analyze the patient's heart rhythm and determine whether a shock is advised.
SMART biphasic waveform	The patented, low-energy defibrillation shock waveform used by the FR2+. It is an impedance-compensated biphasic waveform with 150 Joules, nominal, delivered to a 50 ohm load. When delivered via FR2 infant/child reduced-energy defibrillator pads, the energy is attenuated to 50 Joules, nominal.
specificity	A measure of the ability of the HeartStart FR2+ to reliably detect and identify non-shockable heart rhythms.
standard battery	The M3863A battery, 12 VDC, 4.2 Ah, lithium manganese dioxide, disposable, long-life primary cell.
standby mode	The operating mode of the HeartStart FR2+ when a battery has been installed, and the unit is turned off and ready for use when needed. Shown by flashing black hourglass on the Status Indicator.
status indicator	This is a special window in the upper right-hand corner of the front panel of the HeartStart FR2+ that lets you know the status of the device.
sudden cardiac arrest	The sudden cessation of the heart's pumping rhythm.

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M3860A/M3861A HEARTSTART FR2+

training & administration pack	An optional accessory for the FR2+ that enables training and administrative functions. The integral battery should be charged only using the M3855A charger.
waveform	See "SMART biphasic waveform."
write (data)	A feature of the HeartStart FR2+ that allows it to record setup information on a data card.

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